

EXHIBIT B

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SUPERIOR COURT OF NEW JERSEY
LAW DIVISION - ATLANTIC COUNTY

CIVIL ACTION

- - -

IN RE: :CASE NO.
:291 CT
:PELVIC MESH/GYNECARE LITIGATION :MASTER CASE
:6341-10

CONFIDENTIAL

SUBJECT TO STIPULATION AND ORDER OF CONFIDENTIALITY

November 13, 2015

Continued videotape realtime deposition
of MARTIN WEISBERG, M.D., was taken pursuant to
notice and held at the law offices of RIKER DANZIG
HYLAND PERRETTI LLP, Headquarters Plaza, One
Speedwell Avenue, Morristown, New Jersey, beginning
at 9:42 a.m. on the above date, before Kimberly A.
Cahill, a Federally Approved Registered Merit
Reporter and Notary Public for the State of New
Jersey.

- - -

GOLKOW TECHNOLOGIES, INC.
877.370.3377 ph|917.591.5672 fax
deps@golkow.com

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<p>1 Transcript of the continued 2 deposition of MARTIN WEISBERG, M.D., called for 3 Videotape Examination in the above-captioned matter, 4 said deposition taken pursuant to Superior Court 5 Rules of Practice and Procedure by and before 6 KIMBERLY A. CAHILL, a Federally Approved Registered 7 Merit Reporter, Certified Court Reporter, and Notary 8 Public for the State of New Jersey, at the offices 9 of RIKER DANZIG SCHERER HYLAND PERRETTI LLP, 10 Headquarters Plaza, One Speedwell Avenue, 11 Morristown, New Jersey, commencing at 9:42 a.m. 12 13 - - - 14 15 16 17 18 19 20 21 22 23 24 25</p>	<p>1 BUTLER SNOW LLP BY: WILLIAM M. GAGE, ESQUIRE 2 1020 Highland Colony Parkway, Suite 1400 Ridgeland, Mississippi 39157 3 (601) 948-5711 william.gage@butlersnow.com 4 Representing the Johnson & Johnson and Ethicon Defendants 5 6 SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP BY: RICHARD T. BERNARDO, ESQUIRE 7 (via telephone) 4 Times Square 8 New York, New York 10036 (212) 735-3453 richard.bernardo@skadden.com 9 Representing the Johnson & Johnson and Ethicon Defendants 10 11 VIDEOTAPE TECHNICIAN: 12 Dale Swindell 13 14 15 16 17 - - - 18 19 20 21 22 23 24 25</p>
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<p>1 APPEARANCES: 2 HEARD ROBINS CLOUD LLP 3 BY: ALEX BARLOW, ESQUIRE 2000 West Loop South 4 22nd Floor Houston, Texas 77027 5 (713) 650-1200 barlow@heardrobins.com 6 Representing the MDL Plaintiffs 7 FREESE & GOSS, PLLC 8 BY: RICHARD A. FREESE, ESQUIRE Regions Harbert Plaza 1901 9 6th Avenue North, Suite 3120 Birmingham, Alabama 35203 10 (205) 871-4144 rich@freeseandgoss.com 11 Representing the Texas Plaintiffs 12 KLINE & SPECTER, P.C. 13 BY: CATHERINE A. FOLEY, ESQUIRE (via telephone) 14 The Nineteenth Floor 1525 Locust Street 15 Philadelphia, Pennsylvania 19102 (215) 772-1000 16 Catherine.Foley@KlineSpecter.com Representing the Plaintiffs 17 RIKER DANZIG SCHERER HYLAND PERRETTI LLP 18 BY: MAHA M. KABBASH, ESQUIRE Headquarters Plaza 19 One Speedwell Avenue Morristown, New Jersey 07962-1981 20 (973) 538-0800 mkabbash@riker.com 21 Representing the Johnson & Johnson and Ethicon Defendants 22 23 24 25</p>	<p>1 - - - 2 I N D E X 3 - - - 4 5 Testimony of: MARTIN WEISBERG, M.D. 6 By Mr. Barlow 304 By Mr. Freese 381 7 By Mr. Gage 457 By Mr. Freese 527 8 By Mr. Barlow 581 By Mr. Gage 603 9 10 - - - 11 E X H I B I T S 12 - - - 13 14 NO. DESCRIPTION PAGE 15 D-1 Ethicon Response to Section 459 39 Request and Attachments, 16 ETH.MESH.22631022 through ETH.MESH.22632029 17 D-2 7/29/14 CAPA-003474, 476 18 ETH.MESH.22625140 through ETH.MESH.22625145 19 D-3 2008 TVT Brochure, 481 20 ETH.MESH.08003279 through ETH.MESH.08003294 21 D-4 2012 TVT Brochure, 483 22 ETH.MESH.09744858 through ETH.MESH.09744863 23 D-5 1/15 E-Mail Chain, 488 24 ETH.MESH.22631008 25 D-6 4/8/15 Cover Letter from 494</p>

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<p>1 Reserved for Confidential Designation Index as 2 Pursuant to the Protective Order 3 - - - 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25</p>	<p>1 BY MR. BARLOW: 2 Q. Good morning, Dr. Weisberg. 3 A. Hello. 4 Q. I'm Alex Barlow. We met yesterday. 5 A. Yes. 6 Q. And I'm going to be continuing with 7 your questioning today. 8 I'm going to hand you a document that 9 I've marked P-1656, and I will represent to you that 10 that is the TVT Abbrevio IFU that Ethicon has 11 produced in this case and represented to us was in 12 use from September 24, 2015 to the present day. 13 Take a look at that and confirm it for me, please. 14 And here, Maha -- I'm sorry, Maha. 15 MR. GAGE: It's probably better to 16 hand them to her because she can kind of look, check 17 in on it and make sure that -- 18 MR. BARLOW: Make sure I'm not -- 19 MR. GAGE: Yep. 20 MR. BARLOW: -- getting the wrong 21 one. 22 MR. GAGE: She's going to go get her 23 chart, but you go ahead and keep going with him. If 24 there's a problem, she'll let us know when she comes 25 back.</p>
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<p>1 - - - 2 THE VIDEO TECHNICIAN: We're now on 3 the record. My name is Dale Swindell. I am a 4 videographer for Golkow Technologies. Today's date 5 is November 13th, 2015 and the time is 9:42 a.m. 6 This video deposition is being held 7 in Morristown, New Jersey in the matter of In Re: 8 Pelvic Mesh/Gynecare (Atlantic). The deponent is 9 Martin Weisberg, M.D. Counsel will be noted on the 10 stenographic record. 11 The court reporter is Kimberly Cahill 12 and will now swear in the witness. 13 - - - 14 MARTIN WEISBERG, M.D., after having 15 been duly sworn, was examined and 16 testified as follows: 17 - - - 18 (Deposition Exhibit No. P-1656, 19 9/24/15-Present TVT Abbrevio IFU, 20 HMESH_ETH_11049264 through 21 HMESH_ETH_11049274, was marked for 22 identification.) 23 - - - 24 EXAMINATION 25 - - -</p>	<p>1 (Pause.) 2 THE WITNESS: Yes. 3 BY MR. BARLOW: 4 Q. And, Doctor, I'm going to ask you -- 5 we're going to go through. I'm going to ask you to 6 compare that to Exhibit 1640, which is the list of 7 adverse reactions for TVT. 8 A. Okay. 9 Q. First, let me ask you about 1640. 10 All of the adverse reactions listed on Exhibit 1640 11 are adverse reactions that can occur with the TVT 12 Abbrevio; correct? 13 A. Yes. 14 Q. And all of the reactions, the adverse 15 reactions, listed on 1640, Exhibit 1640, are adverse 16 reactions that were known to be something that could 17 occur with regard to the TVT family of products when 18 -- at the initial launch of the original TVT; 19 correct? 20 A. I don't know that there was any 21 documentation of excessive contraction at that time. 22 It was hypothetical. 23 Q. It was -- it was known to be a 24 possibility at the launch of the first TVT that 25 excessive contraction was a possibility.</p>

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<p>1 A. I think it was hypothesized.</p> <p>2 Q. When were the first reports of</p> <p>3 excessive contraction that you're aware of?</p> <p>4 A. For TVT?</p> <p>5 Q. Uh-hum.</p> <p>6 A. I don't know that I can recall any</p> <p>7 documentation of excessive contraction. I just</p> <p>8 don't know.</p> <p>9 Q. Okay.</p> <p>10 It was a risk that was considered as</p> <p>11 a reasonable possibility at the launch of the</p> <p>12 original TVT that there could be excessive</p> <p>13 contraction; correct?</p> <p>14 A. Well, it was only hypothesized</p> <p>15 because the device was new.</p> <p>16 Q. What preclinical testing or prelaunch</p> <p>17 clinical testing did you do to exclude the</p> <p>18 possibility of excessive contraction before the</p> <p>19 launch of the original TVT?</p> <p>20 MR. GAGE: Objection; beyond the</p> <p>21 scope.</p> <p>22 THE WITNESS: I don't have that</p> <p>23 information in my head. I would need to look it up.</p> <p>24 BY MR. BARLOW:</p> <p>25 Q. As you sit here today, can you</p>	<p>1 adverse reactions listed on 1640; correct?</p> <p>2 A. If feasible means could it be done --</p> <p>3 could it have been done, yes.</p> <p>4 Q. And it would have been feasible at</p> <p>5 the time of the launch of the TVT Abbrevio to warn of</p> <p>6 all of the adverse reactions listed on 1640;</p> <p>7 correct?</p> <p>8 A. Yes.</p> <p>9 Q. And it would have been reasonable to</p> <p>10 warn of all of the adverse reactions listed on 1640</p> <p>11 at the time of the launch of the Abbrevio; correct?</p> <p>12 A. I'm hesitating because I don't know</p> <p>13 that there was enough evidence to include excessive</p> <p>14 contraction; and then if -- if that evidence did not</p> <p>15 exist, then it might not have been reasonable.</p> <p>16 Q. You don't know one way or the other</p> <p>17 whether or not there was enough evidence of</p> <p>18 excessive contraction at the time of the launch of</p> <p>19 the Abbrevio as to whether or not it would have been</p> <p>20 reasonable to include that?</p> <p>21 A. That's right.</p> <p>22 Q. You included it, obviously, after the</p> <p>23 Health Canada inquiry; correct?</p> <p>24 MR. GAGE: Object to form.</p> <p>25 THE WITNESS: We notified Health</p>
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<p>1 identify any clinical testing that was done on the</p> <p>2 original TVT before launch to inquire about whether</p> <p>3 or not excessive contraction was something more than</p> <p>4 a hypothesized risk?</p> <p>5 MR. GAGE: Objection; beyond the</p> <p>6 scope.</p> <p>7 Go ahead.</p> <p>8 THE WITNESS: I don't recall any.</p> <p>9 BY MR. BARLOW:</p> <p>10 Q. Doctor, with regard to the other</p> <p>11 adverse reactions listed on 1640, were all those</p> <p>12 adverse reactions known by Ethicon to be risk --</p> <p>13 adverse reactions that could occur with the TVT</p> <p>14 family of products at the time of the launch of the</p> <p>15 original TVT?</p> <p>16 A. Yes.</p> <p>17 Q. Doctor, at the time -- strike that.</p> <p>18 It would have been feasible to warn</p> <p>19 of all of the risks listed on Exhibit 1640 at the</p> <p>20 time of the launch of the original TVT, would it</p> <p>21 have -- wouldn't it have?</p> <p>22 A. Feasible --</p> <p>23 Q. Let me ask that again because it was</p> <p>24 a -- at the time of the launch of the original TVT,</p> <p>25 it would have been feasible to warn of all of the</p>	<p>1 Canada that we would include it, yes.</p> <p>2 BY MR. BARLOW:</p> <p>3 Q. You notified Health Canada that you</p> <p>4 would include it, but it did not actually appear in</p> <p>5 the TVT Abbrevio.</p> <p>6 A. That's right.</p> <p>7 Q. IFU.</p> <p>8 A. That's correct.</p> <p>9 Q. With the exception of the excessive</p> <p>10 contraction, all of the adverse reactions listed on</p> <p>11 1640 would have been reasonable to warn of at the</p> <p>12 time of the launch of the Abbrevio; correct?</p> <p>13 A. Yes.</p> <p>14 Q. It would have been reasonable to warn</p> <p>15 of foreign body response resulting in inflammation,</p> <p>16 extrusion, erosion, exposure, and fistula formation;</p> <p>17 correct?</p> <p>18 A. Yes.</p> <p>19 Q. At the time of the launch of the</p> <p>20 Abbrevio, it would have been reasonable to warn of</p> <p>21 mesh extrusion, exposure, and erosion into the</p> <p>22 vagina and other structures or organs; correct?</p> <p>23 A. Yes.</p> <p>24 Q. And it would have been reasonable to</p> <p>25 warn at the time of the launch of the TVT Abbrevio of</p>

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<p>1 acute and chronic pain, wouldn't it have?</p> <p>2 A. Yes.</p> <p>3 Q. It would have been reasonable to warn</p> <p>4 of pain with intercourse with some patients that may</p> <p>5 not resolve at the time of the launch of the TVT</p> <p>6 Abbrevio; correct?</p> <p>7 A. Yes.</p> <p>8 Q. It would have been reasonable to warn</p> <p>9 of neuromuscular problems, including acute and/or</p> <p>10 chronic pain in the groin, thigh, leg, pelvic and</p> <p>11 abdominal area at the time of the launch of the TVT</p> <p>12 Abbrevio, wouldn't it have?</p> <p>13 A. Yes.</p> <p>14 Q. And it would have been reasonable to</p> <p>15 warn at the time of the launch of the TVT Abbrevio of</p> <p>16 the adverse reactions, that they may require</p> <p>17 surgical treatment to cure them; correct?</p> <p>18 A. Yes.</p> <p>19 Q. It would have been reasonable to warn</p> <p>20 at the launch of the TVT Abbrevio that one or more</p> <p>21 revision surgeries may be necessary to treat adverse</p> <p>22 reactions to the TVT Abbrevio. That would have been</p> <p>23 reasonable to warn of at its launch; correct?</p> <p>24 A. Yes.</p> <p>25 Q. It would have also been -- strike</p>	<p>1 original TVT, it would have been reasonable to warn</p> <p>2 of pain with intercourse, which in some patients may</p> <p>3 not resolve; correct?</p> <p>4 A. Yes.</p> <p>5 Q. At the time of the launch of the</p> <p>6 original TVT, it would have been reasonable to warn</p> <p>7 of neuromuscular problems, including acute and/or</p> <p>8 chronic pain in the groin, thigh, leg, pelvic and/or</p> <p>9 abdominal area; correct?</p> <p>10 A. Yes.</p> <p>11 Q. At the time of the launch of the</p> <p>12 original TVT, it would have been reasonable to warn</p> <p>13 that adverse reactions to the TVT may require</p> <p>14 surgical treatment; correct?</p> <p>15 A. Yes. I -- you know what? I think I</p> <p>16 spoke too quickly on one of those and I'd like to go</p> <p>17 back to the -- the thigh and leg pain for the</p> <p>18 original TVT.</p> <p>19 The original TVT did not involve that</p> <p>20 area.</p> <p>21 MR. BARLOW: I'm going to object as</p> <p>22 nonresponsive and I'll ask you a clean question.</p> <p>23 THE WITNESS: Okay.</p> <p>24 BY MR. BARLOW:</p> <p>25 Q. At the time of the launch of the</p>
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<p>1 that.</p> <p>2 It would have been reasonable to warn</p> <p>3 at the time of the launch of the TVT Abbrevio that in</p> <p>4 cases in which Prolene mesh needs to be removed in</p> <p>5 part or in whole, significant dissection may be</p> <p>6 required; correct?</p> <p>7 A. Yes.</p> <p>8 Q. And, Doctor, just so we have the</p> <p>9 record clean, at the time of the launch of the</p> <p>10 original TVT, it would have been reasonable to warn</p> <p>11 of the foreign body response that could result in</p> <p>12 inflammation, extrusion, erosion, exposure, and</p> <p>13 fistula formation; correct?</p> <p>14 A. Yes.</p> <p>15 Q. At the time of the launch of the</p> <p>16 original TVT, it would have been reasonable to warn</p> <p>17 of mesh extrusion, exposure, erosion into the vagina</p> <p>18 and other structures or organs; correct?</p> <p>19 A. Yes.</p> <p>20 Q. At the time of the launch of the TVT,</p> <p>21 it would have been reasonable for Ethicon to warn</p> <p>22 about acute and/or chronic pain in association with</p> <p>23 the TVT; correct?</p> <p>24 A. Yes.</p> <p>25 Q. At the time of the launch of the</p>	<p>1 original TVT, it would have been reasonable to warn</p> <p>2 of neuromuscular problems, including acute and/or</p> <p>3 chronic pain in the groin and/or pelvic and</p> <p>4 abdominal area.</p> <p>5 A. Yes.</p> <p>6 Q. At the time of the launch of the</p> <p>7 original TVT, it would have been reasonable to have</p> <p>8 warned that adverse reactions to the TVT may require</p> <p>9 surgical treatment; correct?</p> <p>10 A. Yes.</p> <p>11 Q. And it would have been -- strike</p> <p>12 that.</p> <p>13 It would have been reasonable to warn</p> <p>14 at the time of the launch of the original TVT that</p> <p>15 one or more revision surgeries may be necessary to</p> <p>16 treat adverse reactions to the TVT; correct?</p> <p>17 A. Yes.</p> <p>18 Q. It would have been reasonable to warn</p> <p>19 at the time of the launch of the original TVT that</p> <p>20 in cases where Prolene mesh needs to be removed in</p> <p>21 part or whole, significant dissection may be</p> <p>22 required; correct?</p> <p>23 A. Yes.</p> <p>24 Q. And, Doctor, I'm going to go through</p> <p>25 the same questions with the TVT-O and then we'll</p>

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<p>1 move forward. Okay?</p> <p>2 A. Okay.</p> <p>3 Q. At the time of the launch of the</p> <p>4 TVT-O, it would have been reasonable for Ethicon to</p> <p>5 warn that foreign body response to the TVT-O could</p> <p>6 result in inflammation, extrusion, erosion,</p> <p>7 exposure, and fistula formation; correct?</p> <p>8 A. Yes.</p> <p>9 Q. It was something that was known to</p> <p>10 Ethicon at the time of the launch of the TVT-O that</p> <p>11 the foreign body response to the TVT-O can result in</p> <p>12 inflammation, extrusion, erosion, exposure, and</p> <p>13 fistula formation; correct?</p> <p>14 A. Yes.</p> <p>15 Q. It was something that was known to</p> <p>16 Ethicon at the time of the launch of the TVT-O that</p> <p>17 mesh extrusion, exposure, and erosion into the</p> <p>18 vagina or other structures or organs could occur</p> <p>19 with the TVT-O; correct?</p> <p>20 A. Yes.</p> <p>21 Q. It would have been reasonable for</p> <p>22 Ethicon to warn the doctors and consumers that mesh</p> <p>23 extrusion, exposure, or erosion into the vagina or</p> <p>24 other structures or organs could occur with the</p> <p>25 TVT-O at the time of its launch; correct?</p>	<p>1 TVT-O device, it would have been reasonable for</p> <p>2 Ethicon to have warned that acute or chronic pain</p> <p>3 could result from the device.</p> <p>4 A. The reason I'm hesitating is because</p> <p>5 the device is part of the procedure and it's hard to</p> <p>6 know what the pain is from, whether it's from the</p> <p>7 device or from the procedure, but --</p> <p>8 Q. Doctor, it would have been reasonable</p> <p>9 to warn that -- at the time of the launch of the</p> <p>10 TVT-O, that use of the product could result in acute</p> <p>11 and/or chronic pain.</p> <p>12 A. Yes.</p> <p>13 Q. It would have been reasonable to warn</p> <p>14 at the time -- strike that.</p> <p>15 It was known to Ethicon at the time</p> <p>16 of the launch of the TVT-O that pain with</p> <p>17 intercourse, which in some patients may not resolve,</p> <p>18 may result from use of the TVT-O.</p> <p>19 A. Yes.</p> <p>20 Q. And it would have been reasonable to</p> <p>21 warn at the time of the launch of the TVT-O that</p> <p>22 pain with intercourse, which in some patients may</p> <p>23 not resolve, could result from use of the TVT-O;</p> <p>24 correct?</p> <p>25 A. Yes.</p>
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<p>1 MR. GAGE: Object to form.</p> <p>2 THE WITNESS: Yes.</p> <p>3 MR. BARLOW: Because of the</p> <p>4 objection, let me ask it a different way.</p> <p>5 BY MR. BARLOW:</p> <p>6 Q. Doctor, it would have been reasonable</p> <p>7 for Ethicon to warn with regard to the TVT-O at the</p> <p>8 time of its launch that mesh extrusion, exposure, or</p> <p>9 erosion into the vagina or other structures or</p> <p>10 organs could occur with the TVT-O; correct?</p> <p>11 A. Yes.</p> <p>12 Q. It was known to Ethicon at the time</p> <p>13 of the launch of the TVT-O that acute and/or chronic</p> <p>14 pain could result from the TVT-O; correct?</p> <p>15 A. Yes.</p> <p>16 Q. It was also -- well, strike that.</p> <p>17 It was reasonable -- it would have</p> <p>18 been reasonable for Ethicon to warn at the time of</p> <p>19 the launch of the TVT-O that acute and/or chronic</p> <p>20 pain could result from the TVT-O; correct?</p> <p>21 A. From the procedure? Or from the</p> <p>22 device?</p> <p>23 MR. BARLOW: Object as nonresponsive.</p> <p>24 BY MR. BARLOW:</p> <p>25 Q. At the time of the launch of the</p>	<p>1 Q. And it was known to -- strike that.</p> <p>2 It was known to Ethicon at the time</p> <p>3 that the TVT-O was launched that neuromuscular</p> <p>4 problems, including acute and/or chronic pain in the</p> <p>5 groin, thigh, leg, pelvic and/or abdominal area</p> <p>6 could result from the use of the TVT-O; correct?</p> <p>7 A. Yes.</p> <p>8 Q. And at the time -- it would have been</p> <p>9 reasonable to warn at the time of the launch of the</p> <p>10 TVT-O that neuromuscular problems, including acute</p> <p>11 and/or chronic pain in the groin, thigh, leg, pelvic</p> <p>12 and abdominal area could result, correct, from its</p> <p>13 use?</p> <p>14 A. Yes.</p> <p>15 Q. It was known to Ethicon at the time</p> <p>16 of the launch of the TVT-O that the adverse</p> <p>17 reactions to the TVT-O may require surgical</p> <p>18 treatment; correct?</p> <p>19 A. Yes.</p> <p>20 Q. It would have been reasonable for</p> <p>21 Ethicon to have warned at the time of the launch of</p> <p>22 the TVT-O that adverse reactions may require</p> <p>23 surgical treatment; correct?</p> <p>24 A. Yes.</p> <p>25 Q. It was known to Ethicon at the time</p>

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<p style="text-align: right;">Page 318</p> <p>1 of the launch of the TVT-O that one or more revision 2 surgeries may be necessary to treat the adverse 3 reactions to the TVT-O; correct? 4 A. Yes. 5 Q. And at the time of the launch of the 6 TVT-O, it would have been reasonable for Ethicon to 7 warn that one or more revision surgeries may be 8 necessary to treat the adverse reactions from its 9 use; correct? 10 A. Yes. 11 Q. Doctor, at the time of the launch of 12 the TVT-O, it was known to Ethicon -- strike that. 13 I've got a dry mouth. I'm sorry. 14 MS. KABBASH: Alex, while you've 15 stopped, I don't know if we need to go off. There's 16 an attorney who can't dial in because he says the 17 number from yesterday is not working. 18 Is there a different number today? 19 THE VIDEO TECHNICIAN: We'll go off 20 the record? 21 MS. KABBASH: Yeah. 22 THE VIDEO TECHNICIAN: The time is 23 9:59. We're going off the record. 24 - - - 25 (A discussion off the record)</p>	<p style="text-align: right;">Page 320</p> <p>1 Q. It was known to Ethicon at the time 2 of the launch of the original TVT that mesh 3 extrusion, exposure, or erosion into the vagina or 4 other structures or organs could occur as a result 5 of the use of the TVT; correct? 6 A. Yes. 7 Q. It was known by Ethicon at the time 8 of the launch of the original TVT that acute and/or 9 chronic pain could result from its use; correct? 10 A. Yes. 11 Q. It was known by Ethicon at the time 12 of the launch of the original TVT that pain with 13 intercourse, which in some patients may not resolve, 14 could result from the use of the TVT; correct? 15 A. Yes. 16 Q. It was known by Ethicon at the time 17 of the launch of the original TVT that neuromuscular 18 problems, including acute and/or chronic pain in the 19 groin, pelvis, and abdominal area could result from 20 the use of the TVT; correct? 21 A. Yes. 22 Q. It was known by Ethicon at the time 23 of the launch of the original TVT that the adverse 24 reactions that could occur as a result of its use 25 may require surgical treatment; correct?</p>
<p style="text-align: right;">Page 319</p> <p>1 occurred.) 2 - - - 3 THE VIDEO TECHNICIAN: The time is 4 10:02. We're back on the record. 5 BY MR. BARLOW: 6 Q. Doctor, now that I've got some water 7 and not choking, we'll take up the questions again. 8 At the time of the launch of the 9 TVT-O, it was known to Ethicon that in cases in 10 which the Prolene mesh needed to be removed in part 11 or whole, significant dissection may be required; 12 correct? 13 A. Yes. 14 Q. And it would have been reasonable at 15 the time of the launch of the TVT-O for Ethicon to 16 warn that in cases in which the Prolene mesh needs 17 to be removed in part or whole, significant 18 dissection may be required; correct? 19 A. Yes. 20 Q. And, Doctor, at the time of the 21 launch of the TVT -- the original TVT, it was known 22 to Ethicon that the foreign body response could 23 result in inflammation, extrusion, erosion, 24 exposure, and fistula formation; correct? 25 A. Yes.</p>	<p style="text-align: right;">Page 321</p> <p>1 A. Yes. 2 Q. It was known at the time of the 3 launch of the original TVT that one or more revision 4 surgeries may be necessary to treat the adverse 5 reactions to the TVT's use; correct? 6 A. Yes. 7 Q. In cases in which -- strike that. 8 It was known to Ethicon at the time 9 of the launch of the original TVT that in cases in 10 which the Prolene mesh used in the TVT needed to be 11 removed in part or whole, significant dissection may 12 be required; correct? 13 A. Yes. 14 Q. Doctor, it was known at the time of 15 the launch of the original TVT that even when 16 additional surgeries were performed, that the 17 adverse reactions and the symptoms related to them 18 may not resolve; correct? 19 A. That's correct. 20 Q. And that -- it was known at the time 21 of the launch of the TVT-O that even with additional 22 surgeries to treat the adverse reactions that may 23 occur with the TVT-O, those adverse reactions or the 24 symptoms related to them may not resolve; correct? 25 A. That's correct.</p>

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<p>1 Q. And it was known at the time of the</p> <p>2 launch of the TVT Abbrevio that even with surgeries</p> <p>3 to correct the adverse reactions to the TVT Abbrevio,</p> <p>4 that the symptoms or the adverse reactions may not</p> <p>5 resolve; correct?</p> <p>6 A. Yes.</p> <p>7 Q. And it would have been reasonable at</p> <p>8 the time of the launch of the TVT Abbrevio to warn</p> <p>9 about the possibility that additional surgeries may</p> <p>10 not cure the symptoms or adverse reactions; correct?</p> <p>11 A. Yes.</p> <p>12 Q. It would have been reasonable to warn</p> <p>13 at the time of the launch of the original TVT that</p> <p>14 additional surgeries may not resolve the adverse</p> <p>15 reactions or the related symptoms to the use of the</p> <p>16 TVT; correct?</p> <p>17 A. Correct.</p> <p>18 Q. And it would have been reasonable for</p> <p>19 -- strike that.</p> <p>20 At the time of the launch of the</p> <p>21 TVT-O, it would have been reasonable for Ethicon to</p> <p>22 warn that additional surgeries to treat adverse</p> <p>23 reactions may not resolve those adverse reactions or</p> <p>24 symptoms; correct?</p> <p>25 A. Correct.</p>	<p>1 A. Yes.</p> <p>2 Q. It was known by Ethicon at the time</p> <p>3 of the launch of the original TVT-O that de novo</p> <p>4 urinary retention could result from its use;</p> <p>5 correct?</p> <p>6 A. Yes.</p> <p>7 Q. It was known by Ethicon at the time</p> <p>8 of the launch of the original TVT that urinary</p> <p>9 obstruction -- de novo urinary obstruction could</p> <p>10 result from its use; correct?</p> <p>11 A. Yes.</p> <p>12 Q. It was known at the time of the</p> <p>13 launch of the original TVT that de novo voiding</p> <p>14 dysfunction could result from its use; correct?</p> <p>15 A. Yes.</p> <p>16 Q. Doctor, at the time of the launch of</p> <p>17 the TVT-O, it was known that de novo urge</p> <p>18 incontinence could result from its use; correct?</p> <p>19 A. Yes.</p> <p>20 Q. At the time of the launch of the</p> <p>21 TVT-O, it was known that de novo urinary infrequency</p> <p>22 -- urinary frequency could result from its use;</p> <p>23 correct?</p> <p>24 A. Yes.</p> <p>25 Q. At the time of the launch of the</p>
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<p>1 Q. Doctor, let me turn your attention to</p> <p>2 Exhibit 1641.</p> <p>3 A. Okay.</p> <p>4 Q. Doctor, at the time of the launch of</p> <p>5 the original TVT, it was known to Ethicon that urge</p> <p>6 incontinence could result from its use; correct?</p> <p>7 A. Yes.</p> <p>8 Q. At the time of the launch of the</p> <p>9 original TVT, it was known to Ethicon that urinary</p> <p>10 frequency could result from the TVT's use; correct?</p> <p>11 A. Yes.</p> <p>12 Q. And this would be de novo urinary</p> <p>13 frequency. Right?</p> <p>14 A. Yes.</p> <p>15 Q. And, Doctor, let me go back and clean</p> <p>16 it up.</p> <p>17 At the time of the launch of the</p> <p>18 original TVT, it was known to Ethicon that de novo</p> <p>19 urge incontinence could result from its use;</p> <p>20 correct?</p> <p>21 A. Yes.</p> <p>22 Q. And at the time of the launch of the</p> <p>23 original TVT, it was known that de novo urge --</p> <p>24 urinary frequency could result from its use;</p> <p>25 correct?</p>	<p>1 original -- of the TVT-O, it was known that de novo</p> <p>2 urinary retention could result from its use,</p> <p>3 correct, by Ethicon?</p> <p>4 A. Yes.</p> <p>5 Q. That was known.</p> <p>6 It was known by Ethicon at the time</p> <p>7 of the launch of TVT-O that de novo urinary</p> <p>8 obstruction could occur from its use; correct?</p> <p>9 A. Yes.</p> <p>10 Q. And it was known by Ethicon at the</p> <p>11 time of the TVT-O's launch that de novo voiding</p> <p>12 dysfunction could result from its use; correct?</p> <p>13 A. Yes.</p> <p>14 Q. Doctor, at the time of the launch of</p> <p>15 the original TVT, it would have been reasonable for</p> <p>16 Ethicon to warn that de novo urge incontinence could</p> <p>17 result from its use; correct?</p> <p>18 A. Yes.</p> <p>19 Q. At the time of the launch of the</p> <p>20 original TVT, it would have been reasonable for</p> <p>21 Ethicon to warn that de novo urinary frequency could</p> <p>22 result from its use; correct?</p> <p>23 A. Yes.</p> <p>24 Q. At the time of the launch of the</p> <p>25 original TVT, it was -- it would have been</p>

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<p>1 reasonable for Ethicon to have warned that de novo 2 urinary retention could result from its use; 3 correct? 4 A. Yes. 5 Q. At the time of the launch of the 6 original TVT, it would have been reasonable for 7 Ethicon to have warned that de novo urinary 8 obstruction could result from its use; correct? 9 A. Yes. 10 Q. At the time of the launch of the 11 original TVT, it would have been reasonable for 12 Ethicon to have warned that de novo voiding 13 dysfunction could result from its use; correct? 14 A. Yes. 15 Q. Doctor, at the time of the launch of 16 the TVT-O, it would have been reasonable for Ethicon 17 to warn that de novo urge incontinence could result 18 from its use; correct? 19 A. Yes. 20 Q. At the time of the launch of the 21 TVT-O, it would have been reasonable for Ethicon to 22 have warned that de novo urinary frequency could 23 result from its use; correct? 24 A. Yes. 25 Q. At the time of the launch of the</p>	<p>1 A. Yes. 2 Q. At the time of the launch of the 3 Abbrevo, it was known by Ethicon that de novo 4 urinary retention could result from its use; 5 correct? 6 A. Yes. 7 Q. At the time of the launch of the TVT 8 Abbrevo, it was known that de novo urinary 9 obstruction could result from its use; correct? 10 A. Yes. 11 Q. At the time of the launch of the TVT 12 Abbrevo, it was known by Ethicon that de novo 13 voiding dysfunction could result from its use; 14 correct? 15 A. Yes. 16 Q. Doctor, at the time of the launch of 17 the Abbrevo, it would have been reasonable for 18 Ethicon to warn that de novo urge incontinence could 19 result from its use; correct? 20 A. Yes. 21 Q. At the time of the launch of the TVT 22 Abbrevo, it would have been reasonable for Ethicon 23 to warn that de novo urinary frequency could result; 24 correct? 25 A. Yes.</p>
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<p>1 TVT-O, it would have been reasonable for Ethicon to 2 have warned that de novo urinary retention could 3 result from its use; correct? 4 A. Yes. 5 Q. At the time of the launch of the 6 TVT-O, it would have been reasonable for Ethicon to 7 have warned that de novo urinary obstruction could 8 result from its use; correct? 9 A. Yes. 10 Q. At the time of the launch of the 11 TVT-O, it would have been reasonable for Ethicon to 12 warn of de novo voiding dysfunction resulting from 13 its use; correct? 14 A. Yes. 15 Q. Doctor, at the time of the launch of 16 the Abbrevo, it would have been reasonable -- strike 17 that. 18 At the time of the launch of the 19 Abbrevo, it was known to Ethicon that de novo urge 20 incontinence could result from its use; correct? 21 A. Yes. 22 Q. At the time of the launch of the 23 Abbrevo, it was known to Ethicon that de novo 24 urinary frequency could result from its use; 25 correct?</p>	<p>1 Q. At the time of the launch of the TVT 2 Abbrevo, it would have been reasonable for Ethicon 3 to have warned that de novo urinary retention could 4 result from the Abbrevo; correct? 5 A. Yes. 6 Q. At the time of the launch of the TVT 7 Abbrevo, it would have been reasonable for Ethicon 8 to warn that de novo urinary obstruction could 9 result from the Abbrevo; correct? 10 A. Yes. 11 Q. At the time of the launch of the TVT 12 Abbrevo, it would have been reasonable for Ethicon 13 to have warned that de novo voiding dysfunction 14 could result from the Abbrevo; correct? 15 A. Yes. 16 Q. Okay. 17 Doctor, of the adverse reactions 18 listed in 1640, I want you to compare that to 19 Exhibit 1656. Okay? The TVT Abbrevo IFU? 20 A. Yes. 21 Q. Are all of the adverse reactions 22 listed in 1640, do they appear in 1656? 23 A. Mesh contraction does not. The 24 excessive contraction or shortening of the tissue 25 surrounding the mesh is not.</p>

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<p>1 Q. With the exception of contraction, do</p> <p>2 all of the adverse reactions listed on 1640 appear</p> <p>3 in the Abbrevio?</p> <p>4 A. Yes.</p> <p>5 Q. And with regard to contraction,</p> <p>6 Ethicon informed Health Canada that contraction --</p> <p>7 excess contraction would be included, but that has</p> <p>8 not yet occurred; correct?</p> <p>9 A. Yes.</p> <p>10 Q. So, Doctor, I guess it makes it -- so</p> <p>11 the record's clean, just let me quickly do this:</p> <p>12 Foreign body response resulting in inflammation,</p> <p>13 extrusion, erosion, exposure, and fistula formation</p> <p>14 appears in the current TVT Abbrevio, which is Exhibit</p> <p>15 1656; correct?</p> <p>16 A. Yes.</p> <p>17 (Pause.)</p> <p>18 BY MR. BARLOW:</p> <p>19 Q. Doctor, foreign body response</p> <p>20 resulting in inflammation, extrusion, erosion,</p> <p>21 exposure, and fistula formation appears in the</p> <p>22 current TVT Abbrevio IFU, which is Exhibit 1656;</p> <p>23 correct?</p> <p>24 A. Yes.</p> <p>25 MR. GAGE: Hang on. You --</p>	<p>1 MR. BARLOW: Well, I'm not quoting</p> <p>2 it. I'm just asking if those appear in there.</p> <p>3 MR. GAGE: Oh, oh, oh, oh, oh. Okay.</p> <p>4 So you have to listen very carefully because I don't</p> <p>5 think you understood what he was asking you.</p> <p>6 All right.</p> <p>7 MR. FREESE: I think you're the one</p> <p>8 that didn't understand. I understood and I think</p> <p>9 the doctor understood.</p> <p>10 MR. GAGE: No, he said -- but he</p> <p>11 answered, yes, it does appear.</p> <p>12 MR. BARLOW: It does.</p> <p>13 MR. FREESE: It does.</p> <p>14 THE WITNESS: Not --</p> <p>15 MR. GAGE: Not some of the words you</p> <p>16 had in the question. Anyway, I'm -- look, if I</p> <p>17 messed it up, I'm sorry. I'm -- go ahead.</p> <p>18 THE WITNESS: Okay.</p> <p>19 MR. GAGE: You now have your eyes on</p> <p>20 the language and he can ask you the question.</p> <p>21 THE WITNESS: Okay.</p> <p>22 MR. GAGE: Okay.</p> <p>23 BY MR. BARLOW:</p> <p>24 Q. Okay. Doctor, foreign -- there is a</p> <p>25 foreign body response that could result in</p>
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<p>1 MR. BARLOW: Or is that incorrect?</p> <p>2 MR. GAGE: I don't think he -- could</p> <p>3 you -- let him find --</p> <p>4 MR. BARLOW: Sure.</p> <p>5 MR. GAGE: -- where it is because I'm</p> <p>6 not sure he knows -- he's struggling to find it.</p> <p>7 MR. BARLOW: Let me see if I can find</p> <p>8 it.</p> <p>9 MR. GAGE: No, I don't -- that's not</p> <p>10 his question, though.</p> <p>11 THE WITNESS: Did I misunderstand</p> <p>12 your question?</p> <p>13 MR. GAGE: Yeah.</p> <p>14 THE WITNESS: Maybe I ought to listen</p> <p>15 to your question again.</p> <p>16 MR. BARLOW: Okay.</p> <p>17 THE WITNESS: I think it's the second</p> <p>18 adverse reaction.</p> <p>19 (Pause.)</p> <p>20 MR. BARLOW: I think it's the third</p> <p>21 bullet point under adverse reactions.</p> <p>22 MR. GAGE: Okay. And I think what</p> <p>23 got me was that your -- the actual text of your</p> <p>24 question was not matching up with the actual wording</p> <p>25 in that third bullet point, I think.</p>	<p>1 extrusion, erosion, exposure, fistula formation,</p> <p>2 and/or inflammation appears in the -- the current</p> <p>3 TVT Abbrevio IFU; correct?</p> <p>4 A. Yes.</p> <p>5 Q. And it appears under the -- in the</p> <p>6 adverse reactions section; correct?</p> <p>7 A. Yes.</p> <p>8 Q. Doctor, on the -- with the exception</p> <p>9 of the excess contraction, which we've already</p> <p>10 discussed, do all of the adverse reactions listed on</p> <p>11 1640 appear in the current TVT Abbrevio IFU?</p> <p>12 A. Just give me a moment.</p> <p>13 Q. Sure.</p> <p>14 A. Yes.</p> <p>15 Q. And, Doctor, turning to page --</p> <p>16 strike that -- Exhibit 1641, do all of the TVT</p> <p>17 urinary adverse reactions listed there appear in the</p> <p>18 current TVT Abbrevio IFU?</p> <p>19 A. Yes.</p> <p>20 - - -</p> <p>21 (Deposition Exhibit No. P-1657,</p> <p>22 9/10/10-11/27/14 TVT Abbrevio IFU,</p> <p>23 ETH.MESH.02341203 through</p> <p>24 ETH.MESH.02341213, was marked for</p> <p>25 identification.)</p>

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<p>1 - - -</p> <p>2 BY MR. BARLOW:</p> <p>3 Q. Doctor, I'm going to hand you what</p> <p>4 I've marked as P-1657, and I'll represent to you</p> <p>5 that this is the TVT Abbrevio IFU in use from 9 --</p> <p>6 September 10, 2010 until November 27th, 2014.</p> <p>7 A. That's correct.</p> <p>8 Q. Okay.</p> <p>9 Doctor, before we -- I question you</p> <p>10 further on this, I'm looking at the -- do you have</p> <p>11 the chart?</p> <p>12 Have we marked this as an exhibit,</p> <p>13 the chart of the IFUs with dates? Is that an</p> <p>14 exhibit yet?</p> <p>15 MS. KABBASH: I don't think it's been</p> <p>16 marked.</p> <p>17 MR. BARLOW: Let's go ahead and do</p> <p>18 that. Do you have a chart that we can mark it?</p> <p>19 MR. GAGE: Yeah.</p> <p>20 MR. BARLOW: If it's got your writing</p> <p>21 on it, maybe we can get another copy.</p> <p>22 THE WITNESS: I don't think it does.</p> <p>23 MR. GAGE: I don't think it does.</p> <p>24 Let me see. No. You've got an exhibit sticker?</p> <p>25 MR. BARLOW: Yeah. Let's mark the</p>	<p>1 MR. GAGE: I didn't know it was on</p> <p>2 the exhibit.</p> <p>3 MR. BARLOW: I can sit here and read</p> <p>4 verbatim what's in front of me like a champ --</p> <p>5 actually, that's not true.</p> <p>6 BY MR. BARLOW:</p> <p>7 Q. All right. I'm looking on this</p> <p>8 chart. I'm a little bit confused -- so maybe I</p> <p>9 can't -- I'm looking at the Abbrevio IFUs and we've</p> <p>10 got first use date and last use date.</p> <p>11 Now, the -- what I've -- the IFU that</p> <p>12 I've just marked as 1657, the first use date is</p> <p>13 September 10, 2010 and the last use date is listed</p> <p>14 as 11/27/2014?</p> <p>15 A. Yes.</p> <p>16 Q. And then if you go to the next IFU --</p> <p>17 which I guess we'll go ahead and mark as P-1659.</p> <p>18 - - -</p> <p>19 (Deposition Exhibit No. P-1659,</p> <p>20 7/1/15-9/15/15 TVT Abbrevio IFU,</p> <p>21 ETH.MESH.02617489 through</p> <p>22 ETH.MESH.02617499, was marked for</p> <p>23 identification.)</p> <p>24 - - -</p> <p>25 MR. BARLOW: I'll give you a copy of</p>
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<p>1 chart of IFUs for the various TVT family of products</p> <p>2 and the -- does this have the pelvic organ prolapse</p> <p>3 products on it, too?</p> <p>4 MS. KABBASH: It does.</p> <p>5 MR. BARLOW: Okay -- and the pelvic</p> <p>6 organ prolapse products that was produced to us by</p> <p>7 Ethicon and it's titled "Updated IFU Index and</p> <p>8 Production Bates Range Chart," and we're going to</p> <p>9 mark it as P-1658.</p> <p>10 - - -</p> <p>11 (Deposition Exhibit No. P-1658,</p> <p>12 11/6/15 Updated IFU Index and Production</p> <p>13 Bates Range Chart, was marked for</p> <p>14 identification.)</p> <p>15 - - -</p> <p>16 MR. GAGE: And, Alex, for the record,</p> <p>17 can we identify the date, or the approximate date,</p> <p>18 when this one was produced to plaintiffs?</p> <p>19 MR. BARLOW: This one was produced to</p> <p>20 plaintiffs on 11/6/15.</p> <p>21 MR. GAGE: Perfect. Thank you.</p> <p>22 MR. FREESE: Answer man.</p> <p>23 MR. BARLOW: I can read.</p> <p>24 MR. FREESE: Shell answer man.</p> <p>25 MR. BARLOW: That's right.</p>	<p>1 it, Doctor.</p> <p>2 BY MR. BARLOW:</p> <p>3 Q. It has a first use date of July 1st,</p> <p>4 2015 and a last use date of September 15, 2015. Do</p> <p>5 you see that?</p> <p>6 A. Yes.</p> <p>7 Q. There appears to me to be a gap</p> <p>8 between the Abbrevio -- one IFU to the next for the</p> <p>9 Abbrevio. Do you know why that is?</p> <p>10 A. I don't know specifically in this</p> <p>11 case.</p> <p>12 Q. Do you have an idea of what that</p> <p>13 might be?</p> <p>14 A. Well, it -- the first use date is the</p> <p>15 date of the beginning of the run of manufacturing</p> <p>16 the device in which this was to be used. I don't</p> <p>17 know whether there was a run between 11/27/14 and</p> <p>18 7/1/15. They may have had enough product that they</p> <p>19 didn't do another run.</p> <p>20 I'm not sure of that. That's just</p> <p>21 one possible explanation that I've seen in other</p> <p>22 cases.</p> <p>23 Q. So, in other words, it could be that</p> <p>24 there was enough back stock, I guess, of the Abbrevio</p> <p>25 that already had the first IFU in the packaging, and</p>

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<p>1 a new IFU wasn't produced until you got through that</p> <p>2 stock.</p> <p>3 A. Well, the new IFU may have been</p> <p>4 produced, but it wasn't --</p> <p>5 Q. Put into use.</p> <p>6 A. The line -- yeah, the manufacture of</p> <p>7 the product in which it was going to be inserted --</p> <p>8 used didn't happen until 7/17/15, and that is a</p> <p>9 guess because I don't know for sure.</p> <p>10 Q. You don't know sitting here.</p> <p>11 Do you all know?</p> <p>12 MR. GAGE: Alex, counsel knows --</p> <p>13 MS. KABBASH: He's actually correct.</p> <p>14 So the reason why there's a gap is that the</p> <p>15 company's not making batches every day, so the IFU</p> <p>16 will be approved for use. It will enter the bill of</p> <p>17 materials, which is like a recipe for the batch.</p> <p>18 The first use date will be day one</p> <p>19 that the batch is made that that IFU is going into,</p> <p>20 and then the last use date is day one of the batch</p> <p>21 -- the last batch that that IFU goes into.</p> <p>22 So the next batch that's made might</p> <p>23 be a couple months down the road because they just</p> <p>24 don't need to make another batch. So that explains</p> <p>25 --</p>	<p>1 indicated to be transitory; correct?</p> <p>2 A. That's correct.</p> <p>3 Q. In the current TVT Abbrevio IFU, it is</p> <p>4 noted that the local -- there is no indication that</p> <p>5 the local irritation is transitory; correct?</p> <p>6 MR. GAGE: Which one is the current?</p> <p>7 Is it 1659?</p> <p>8 THE WITNESS: Is that 1659?</p> <p>9 MR. BARLOW: Actually, current is</p> <p>10 1656.</p> <p>11 MR. GAGE: Oh, here it is. I'm</p> <p>12 sorry.</p> <p>13 MR. BARLOW: Strike that. I withdraw</p> <p>14 the question.</p> <p>15 MR. GAGE: Okay.</p> <p>16 MR. BARLOW: Withdrawn.</p> <p>17 BY MR. BARLOW:</p> <p>18 Q. Doctor, the foreign body response</p> <p>19 with regard to the TVT Abbrevio can be chronic, can't</p> <p>20 it?</p> <p>21 A. Histologically, yes.</p> <p>22 Q. Chronic foreign body response is not</p> <p>23 in the TVT Abbrevio listed -- or listed in the</p> <p>24 adverse reactions under the -- strike that.</p> <p>25 Chronic foreign body response is not</p>
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<p>1 MR. BARLOW: Okay. I get it. I just</p> <p>2 was confused. I wanted to make sure we weren't</p> <p>3 missing one.</p> <p>4 BY MR. BARLOW:</p> <p>5 Q. All right, Doctor. Then let's talk</p> <p>6 about the TVT Abbrevio IFU that I've marked as</p> <p>7 P-1657, which was in use from September 10, 2010</p> <p>8 until November 27th, 2014. Okay?</p> <p>9 A. Yes.</p> <p>10 Q. Doctor, does the adverse reaction of</p> <p>11 foreign body response resulting in inflammation,</p> <p>12 extrusion, erosion, exposure, and fistula formation</p> <p>13 appear in that IFU?</p> <p>14 A. Yes.</p> <p>15 Q. Where?</p> <p>16 A. Adverse reactions, second bullet,</p> <p>17 transitory local irritation at the wound site and</p> <p>18 transitory foreign body response may occur. This</p> <p>19 response could result in extrusion, erosion, fistula</p> <p>20 formation, or inflammation.</p> <p>21 Q. Doctor, in the IFU for the Abbrevio,</p> <p>22 which is marked as 1657, the local irritation is</p> <p>23 listed as -- or noted to be transitory; correct?</p> <p>24 A. That's correct.</p> <p>25 Q. And the foreign body response is</p>	<p>1 listed as an adverse reaction in 1657, the TVT</p> <p>2 Abbrevio IFU; correct?</p> <p>3 A. It's not listed in those words. Its</p> <p>4 actions are in the following section.</p> <p>5 Q. Doctor, the words chronic foreign</p> <p>6 body response do not appear in the actions section</p> <p>7 either, do they?</p> <p>8 A. No, they don't.</p> <p>9 Q. In fact, the words chronic foreign</p> <p>10 body response appear nowhere in the TVT Abbrevio IFU</p> <p>11 which has been marked as Exhibit 1657; correct?</p> <p>12 A. That's correct.</p> <p>13 Q. Doctor, does the adverse reaction</p> <p>14 mesh extrusion, exposure, or erosion into the vagina</p> <p>15 or other structures or organs appear in the adverse</p> <p>16 reactions section of the TVT Abbrevio which has been</p> <p>17 marked as Exhibit 16 -- IFU which has been marked as</p> <p>18 Exhibit 1657?</p> <p>19 A. The vagina and other organs is not</p> <p>20 spelled out.</p> <p>21 Q. Doctor, in the adverse reactions</p> <p>22 section of the Abbrevio IFU, which has been marked as</p> <p>23 Exhibit 1657, acute and/or chronic pain does not</p> <p>24 appear; correct?</p> <p>25 A. Correct.</p>

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<p>1 Q. In fact, acute and/or chronic pain 2 does not appear anywhere in the TVT Abbrevio IFU that 3 has been marked as Exhibit 1657; correct? 4 A. 1657 -- wait a minute. Let me make 5 sure I'm on the right one. 6 Q. This is the -- the IFU that was in 7 use from September 2010 to November 2014. 8 A. Yeah, can you ask that question 9 again, please? 10 Q. Sure. 11 A. Or have that read back? 12 Q. Sure. Acute and/or chronic pain does 13 not appear in the TVT Abbrevio IFU that is marked as 14 Exhibit 1657, does it? 15 A. Well, it discusses transient leg pain 16 in the warnings and precautions. 17 Q. Doctor, that transient leg pain does 18 not encompass all of the acute and/or chronic pain 19 that can result from use of the TVT Abbrevio; 20 correct? 21 A. No, it doesn't. 22 Q. And chronic pain appears nowhere in 23 the TVT Abbrevio IFU which has been marked as Exhibit 24 1657, does it? 25 A. That's correct.</p>	<p>1 A. That's correct. 2 Q. And the IFU which has been marked as 3 Exhibit 1657 does not note chronic thigh and leg 4 pain can result from the TVT Abbrevio, does it? 5 A. No, it doesn't. 6 Q. And, Doctor, acute and/or chronic 7 pain in the pelvis and/or abdominal area -- pelvic 8 and/or abdominal area is not listed in the TVT 9 Abbrevio IFU which has been marked as Exhibit 1657; 10 correct? 11 A. Correct. 12 Q. Doctor, the TVT Abbrevio IFU which has 13 been marked as 1657 does not list -- strike that. 14 The TVT Abbrevio IFU which has been 15 marked as Exhibit 1657 does not discuss that adverse 16 reactions may require surgical treatment, does it? 17 A. No. 18 Q. Doctor, the IFU which has been marked 19 as Exhibit 1657 for the Abbrevio does not list that 20 one or more revision surgeries may be necessary to 21 treat the adverse reactions that can result from the 22 Abbrevio, does it? 23 A. No. 24 Q. Doctor, the TVT -- TVT Abbrevio IFU 25 which has been marked as Exhibit 1657 does not</p>
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<p>1 Q. And other than transitory leg pain, 2 acute pain does not occur -- does not appear in the 3 TVT Abbrevio IFU, which has been marked as Exhibit 4 1657; correct? 5 A. The word acute does not. 6 Q. Doctor, is pain with intercourse, 7 which in some patients may not resolve, included in 8 the adverse reactions listed in the TVT Abbrevio IFU 9 which has been marked as Exhibit 1657? 10 A. No. 11 Q. Doctor, do neuromuscular problems, 12 including acute and/or chronic pain in the groin, 13 thigh, leg, pelvic or abdominal area appear in the 14 adverse reactions listed in the TVT Abbrevio IFU 15 which has been marked as 1657? 16 A. No, but leg pain does occur in the 17 warnings and precautions section. 18 Q. Neuromuscular problems is not listed 19 in the adverse reactions section of the TVT Abbrevio 20 IFU, which has been marked as Exhibit 1657; correct? 21 A. Correct. 22 Q. And acute and/or chronic pain in the 23 groin does not appear listed in the adverse 24 reactions that can occur with the TVT Abbrevio; 25 correct?</p>	<p>1 discuss that in cases in which Prolene mesh needs to 2 be removed in part or whole, significant dissection 3 may be required, does it? 4 A. No. 5 Q. And, Doctor, the TVT Abbrevio IFU 6 which has been marked as Exhibit 1657 does not state 7 anywhere in it that even when revision surgeries are 8 performed to treat adverse reactions, that those 9 adverse reactions may not resolve; correct? 10 A. Correct. 11 Q. Doctor, in the TVT Abbrevio IFU, which 12 has been marked as Exhibit 1657, does it warn that 13 de novo urge incontinence can result from the 14 Abbrevio's use? 15 A. No. 16 Q. Doctor, in the TVT Abbrevio IFU that 17 is marked as Exhibit 1657, does it warn that de novo 18 urinary frequency can result from its use? 19 A. No. 20 Q. Doctor, in the TVT Abbrevio IFU which 21 has been marked as Exhibit 1657, does it warn that 22 de novo urinary retention can result from its use? 23 A. Only in reference to lower urinary 24 tract obstruction. 25 Q. And, Doctor, there are other lower --</p>

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<p>1 well, urinary retention is a result of obstruction. 2 Right? 3 A. It can be. 4 Q. Can be. Okay. 5 The TVT Abbrevio IFU that's been 6 marked as Exhibit 1657 does not explicitly list 7 urinary retention as a possibility; correct? 8 A. That's correct, not in those words. 9 Q. It does discuss that de novo 10 obstruction can occur; correct? 11 A. Yes. 12 Q. Okay. 13 Where does it -- point me to that. 14 A. It's the last adverse reaction. 15 Q. Doctor, the obstruction that is noted 16 in the adverse reactions list obstruction resulting 17 from over-tensioning during implant; correct? 18 A. That's correct. 19 Q. Obstruction can also occur with the 20 TVT Abbrevio when there is not over-tensioning by the 21 surgeon; correct? 22 A. Possibly, yes. 23 Q. And that possibility is not listed in 24 the TVT Abbrevio IFU that's marked as Exhibit 1657; 25 correct?</p>	<p>1 regards to over-tensioning; correct? 2 A. That's correct. 3 Q. Doctor, the TVT Abbrevio IFU that's 4 marked as Exhibit 1657 does not warn about the 5 possibility of de novo voiding dysfunction resulting 6 from the Abbrevio, does it? 7 A. Only in the -- when it refers to 8 lower urinary tract obstruction. 9 Q. There are other types of voiding 10 dysfunction; correct? 11 A. Yes. 12 Q. There are other types of voiding 13 dysfunction that can result from the TVT Abbrevio; 14 correct? 15 A. From the procedure in which the TVT 16 Abbrevio's used, yes. 17 Q. There are other types of voiding 18 dysfunction that can result from the use of the TVT 19 Abbrevio; correct? 20 A. Yes. 21 Q. Doctor, let's turn to Exhibit 1659, 22 which I believe is the TVT Abbrevio IFU that was 23 first use date -- that's first use date is July 1, 24 2015 and last use date has been listed as September 25 15, 2015.</p>
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<p>1 A. That's correct. However, it doesn't 2 say by the surgeon. It just says over-tensioning or 3 overcorrection. 4 MR. BARLOW: Move to strike as 5 nonresponsive. 6 THE WITNESS: Okay. 7 BY MR. BARLOW: 8 Q. Doctor, it says, too much tension 9 applied to the mesh implant. Right? 10 A. Yes. 11 Q. That suggests surgeon error; correct? 12 A. Or swelling. 13 Q. Doctor, urinary obstruction can occur 14 with the TVT Abbrevio from scarification; correct? 15 A. It could. 16 Q. Obstruction resulting from 17 scarification with regard to the TVT Abbrevio is not 18 listed as an adverse reaction in the IFU which is 19 marked as Exhibit 1657; correct? 20 A. Correct. 21 Q. And, Doctor, you would agree with me 22 that swelling does not appear anywhere in the TVT 23 Abbrevio IFU; correct? 24 A. That word does not occur. 25 Q. And it doesn't appear in the IFU with</p>	<p>1 A. Yes. 2 Q. Doctor, chronic foreign body response 3 is not listed in the TVT Abbrevio IFU as an adverse 4 reaction; correct? 5 A. Correct. 6 Q. And I'm referring in that instance to 7 the IFU marked as Exhibit 1659. 8 A. Yes. 9 Q. Do you understand that? 10 A. Yes. 11 Q. Doctor, foreign body response 12 resulting in inflammation that is not transitory, 13 it's not listed in the TVT Abbrevio IFU that is 14 marked as Exhibit 1659, is it? 15 A. No. 16 Q. Foreign body response resulting in 17 extrusion -- strike that. 18 Chronic foreign body response 19 resulting in extrusion is not listed in the Abbrevio 20 IFU that has been marked as Exhibit 1659, does it? 21 A. No. 22 MR. GAGE: Let me ask you a question. 23 Is 1659 -- can I just compare quickly? Just a 24 second. 25 (Pause.)</p>

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<p>1 MR. GAGE: All right. I'm sorry, 2 Alex. Go ahead. 3 BY MR. BARLOW: 4 Q. Doctor, chronic foreign body response 5 that can result in erosion is not listed in the 6 adverse reactions in the IFU -- the Abbrevio IFU that 7 has been marked as 1659; correct? 8 A. Correct. 9 Q. Chronic foreign body response that 10 can result in fistula formation is not listed as a 11 possible adverse reaction in the IFU for the Abbrevio 12 that has been marked as Exhibit 1659; correct? 13 A. Correct. 14 Q. The IFU for the Abbrevio that has been 15 marked as Exhibit 1659 does not list chronic foreign 16 body response that can result in inflammation as a 17 possible adverse reaction; correct? 18 A. That's correct. 19 Q. And chronic inflammation is not 20 listed as a possible adverse reaction; correct? 21 A. That's correct. 22 Q. Doctor, the Abbrevio IFU that is 23 marked as Exhibit 1659 does not list as an adverse 24 reaction or warn regarding mesh extrusion, exposure, 25 or erosion into the vagina or other structures or</p>	<p>1 There are neuromuscular problems that 2 can result from the Abbrevio other than leg pain; 3 correct? 4 A. From the procedure in which the 5 Abbrevio is used? 6 Q. There are neuromuscular problems from 7 the use of the TVT Abbrevio that can result other 8 than leg pain; correct? 9 A. Yes. 10 Q. Okay. 11 Doctor, the leg pain that is 12 discussed in the Abbrevio IFU is listed as transient 13 leg pain lasting 24 to 48 hours; correct? 14 A. That's correct. 15 Q. There is no warning regarding the 16 possibility of leg pain lasting beyond 48 hours; 17 correct? 18 A. Not in those words. 19 Q. So, Doctor, the TVT IFU -- strike 20 that. 21 The TVT Abbrevio IFU that's marked as 22 Exhibit 1659 does not list as an adverse reaction 23 neuromuscular problems, including acute and/or 24 chronic pain in the groin, thigh, leg, pelvic and/or 25 abdominal area, does it?</p>
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<p>1 organs, does it? 2 A. The vagina or other structures or 3 organs is not culled out. 4 Q. The IFU for the Abbrevio that is 5 marked as Exhibit 1659 does not list as an adverse 6 reaction acute and/or chronic pain, does it? 7 A. No. 8 Q. The IFU for the Abbrevio that has been 9 marked as Exhibit 1659 does not list as an adverse 10 reaction pain with intercourse, which in some 11 patients may not resolve, does it? 12 A. No. 13 Q. The IFU which -- for the -- strike 14 that. 15 The IFU for the TVT Abbrevio which has 16 been marked as Exhibit 1659 does not list as a 17 adverse reaction neuromuscular problems; correct? 18 A. Only the leg pain noted in warnings 19 and precautions. 20 Q. Doctor, that -- the neuromuscular 21 problems -- strike that. 22 There are neuromuscular problems 23 other than leg pain; correct? 24 A. Yes. 25 Q. All right.</p>	<p>1 A. No, it doesn't. 2 Q. And, Doctor, the TVT Abbrevio does not 3 list as -- chronic thigh pain as an adverse 4 reaction, does it? 5 A. It does not. 6 Q. It does not list chronic leg pain as 7 a possible adverse reaction, does it? 8 A. No. 9 Q. Doctor, the TVT Abbrevio IFU that's 10 marked as Exhibit 1659 does not state that the 11 adverse reactions that may result from the Abbrevio 12 may require surgical treatment, does it? 13 A. It says some of them do. 14 Q. Which ones does it say may result? 15 A. The first adverse reaction, punctures 16 or laceration of vessels, nerves, bladder, urethra, 17 bowel may occur during needle passage and may 18 require surgical repair. 19 Q. Doctor, those are all adverse 20 reactions that may require surgical repair related 21 to the procedure to implant it; correct? 22 A. Correct. 23 Q. With regard to adverse reactions that 24 may -- adverse reactions to the device itself, 25 nowhere in the TVT Abbrevio IFU that's marked as</p>

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<p>1 Exhibit 1659 does it state that there may -- there 2 may be surgical treatment required, does it? 3 A. The device consists of the mesh and 4 the needles to insert the mesh, so if you say due to 5 the device itself, I'd have to say that that's not 6 correct. 7 Q. Doctor, the TVT Abbrevio IFU that's 8 marked as Exhibit 1659 does not state that adverse 9 reactions that may occur postoperatively may require 10 surgical treatment, does it? 11 A. No. 12 Q. And, Doctor, it does not -- the TVT 13 Abbrevio that's marked as Exhibit 1659 does not state 14 that adverse reactions to the sling itself may 15 require surgical treatment, does it? 16 A. No. 17 Q. Doctor, the TVT Abbrevio IFU that's 18 marked as Exhibit 1659 does not state that one or 19 more revision surgeries may be necessary to treat 20 the adverse reactions that occur postoperatively, 21 does it? 22 A. No. 23 Q. The TVT Abbrevio that's marked as 24 Exhibit 1659 does not state that one or more 25 revision surgeries may be necessary to treat adverse</p>	<p>1 - - - 2 (Deposition Exhibit No. P-1660, 3 9/18/15-Present TVT Exact IFU, 4 ETH.MESH.22129185 through 5 ETH.MESH.22129191, was marked for 6 identification.) 7 - - - 8 (Deposition Exhibit No. P-1661, 9 5/4/10-6/6/13 TVT Exact IFU, 10 ETH.MESH.05799233 through 11 ETH.MESH.05799239, was marked for 12 identification.) 13 - - - 14 (Deposition Exhibit No. P-1662, 15 10/23/13-11/26/14 TVT Exact IFU, 16 HMESH_ETH_03038566 through 17 HMESH_ETH_03038572, was marked for 18 identification.) 19 - - - 20 (Deposition Exhibit No. P-1663, 21 8/12/14-9/9/15 TVT Exact IFU, 22 ETH.MESH.02618012 through 23 ETH.MESH.02618018, was marked for 24 identification.) 25 - - -</p>
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<p>1 reactions to the sling itself, does it? 2 A. No. 3 Q. Doctor, the TVT Abbrevio IFU that's 4 marked as Exhibit 1659 does not state that in cases 5 in which the Prolene mesh needs to be removed in 6 part or whole, that significant dissection may be 7 required, does it? 8 A. No. 9 Q. And, Doctor, nowhere in the TVT 10 Abbrevio that's marked as Exhibit 1659 does it state 11 that the surgical repair for possible adverse 12 reactions may not resolve the symptoms or the 13 adverse reactions, does it? 14 A. No. 15 MR. BARLOW: Okay, Doctor. I think 16 we can set aside the Abbrevio stuff for now. We're 17 going to move on to the Exact. 18 MR. GAGE: Yeah, can we take a quick 19 bathroom break? 20 MR. BARLOW: Sure, sure. 21 MR. GAGE: Let's just make it quick. 22 THE VIDEO TECHNICIAN: The time is 23 10:50. We're going off the record. 24 (A recess was taken from 10:50 a.m. 25 until 11:05 a.m.)</p>	<p>1 (Deposition Exhibit No. P-1664, 2 8/5/13-10/17/13 TVT Exact IFU, 3 ETH.MESH.10670138 through 4 ETH.MESH.10670144, was marked for 5 identification.) 6 - - - 7 THE VIDEO TECHNICIAN: The time is 8 11:12. We're back on the record. 9 BY MR. BARLOW: 10 Q. Okay, Doctor. We're going to turn 11 now to the TVT Exact and we're going to try to 12 shorten this process a little bit. 13 I have handed you an exhibit that is 14 marked as P-1660; correct? 15 A. Yes. 16 Q. Okay. 17 And I believe that is the IFU that 18 has been in use from 9/18/2015 to the present day; 19 correct? 20 A. Yes. 21 Q. And then I've handed you several 22 other IF -- well, strike that. 23 I've also handed you an Exhibit 1661 24 that I believe has been represented to us to be the 25 TVT Exact IFU for -- that's been in -- that was in</p>

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<p>1 use from May 4th, 2010 to June 6, 2013.</p> <p>2 Do you have that?</p> <p>3 A. Yes.</p> <p>4 Q. And is that correct?</p> <p>5 A. Yes.</p> <p>6 Q. Okay.</p> <p>7 Exhibit 1662 is the TVT Exact IFU</p> <p>8 that was in use from 10/23/13 until 11/26/14</p> <p>9 according to what has been produced to us; correct?</p> <p>10 A. Yes.</p> <p>11 Q. Exhibit 1663 is the TVT Exact IFU</p> <p>12 that has been represented to be in use from August</p> <p>13 12, 2014 to September 9, 2015; is that correct?</p> <p>14 A. Yes.</p> <p>15 Q. 1664 is the TVT Exact IFU that has</p> <p>16 been represented to be in use from August 5th, 2013</p> <p>17 until October 17th, 2013; correct?</p> <p>18 A. Yes.</p> <p>19 Q. Now, Doctor, on the break, I asked</p> <p>20 you to review Exhibit 1660 through 1664, and you had</p> <p>21 an opportunity to do that. Right?</p> <p>22 A. I did.</p> <p>23 Q. Exhibit 1660 is the TVT Exact IFU</p> <p>24 that was put out as a result of the Health Canada</p> <p>25 inquiry; correct?</p>	<p>1 going to do is, I'm going to ask you questions</p> <p>2 regarding the adverse reactions that would be listed</p> <p>3 in the TVT Exact IFUs that are marked as Exhibits</p> <p>4 1661 through 64.</p> <p>5 And I'm going to ask you that if your</p> <p>6 answer needs to be different for any of the exhibits</p> <p>7 -- the IFUs that are Exhibits 1661 through 1664, you</p> <p>8 tell me; otherwise, we're going to apply your answer</p> <p>9 to each of those individually. Okay?</p> <p>10 THE WITNESS: I'm not sure I followed</p> <p>11 that.</p> <p>12 MR. BARLOW: Okay.</p> <p>13 THE WITNESS: I'm sorry.</p> <p>14 BY MR. BARLOW:</p> <p>15 Q. 1660's obviously different because</p> <p>16 that's the current IFU.</p> <p>17 A. Right. Okay.</p> <p>18 Q. I'm going to be asking you questions</p> <p>19 about 1661 through 1664, which are the out-of-date</p> <p>20 IFUs and -- but I'm going to ask them collectively,</p> <p>21 with the consent of your counsel, and you're going</p> <p>22 to point out to me, if you would, if there needs to</p> <p>23 be a different answer for one of those. Otherwise,</p> <p>24 we're going to apply your answer individually to</p> <p>25 each one of those IFUs. Okay?</p>
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<p>1 A. Yes.</p> <p>2 Q. With regard to Exhibit 1661 through</p> <p>3 1664, you understand I'm going to be questioning you</p> <p>4 regarding warnings and adverse reactions, just as we</p> <p>5 had been discussing earlier; correct?</p> <p>6 A. Correct.</p> <p>7 Q. With regard to the adverse reactions</p> <p>8 listed on Exhibit 1640 and Exhibit 1641, have you</p> <p>9 had an opportunity to review Exhibits 1661 through</p> <p>10 1664 and determine that your answers would be the</p> <p>11 same with regard to all of those IFUs regarding the</p> <p>12 adverse reactions listed in 1640 and 1641?</p> <p>13 A. Let me just understand. My answers</p> <p>14 will be the same for all of these?</p> <p>15 Q. Yes.</p> <p>16 A. Yes.</p> <p>17 Q. Okay.</p> <p>18 MR. GAGE: And to clarify, "these" --</p> <p>19 the word "these" does not include P-1660, which is</p> <p>20 the current --</p> <p>21 MR. BARLOW: Current.</p> <p>22 THE WITNESS: Correct.</p> <p>23 MR. GAGE: -- Abbrevio IFU.</p> <p>24 MR. BARLOW: Yes. Okay.</p> <p>25 With that clarification, what I'm</p>	<p>1 A. Okay. I --</p> <p>2 Q. Is that agreeable?</p> <p>3 A. Yes.</p> <p>4 MR. BARLOW: Counsel, is that</p> <p>5 agreeable?</p> <p>6 MR. GAGE: Yeah, that's fine.</p> <p>7 MR. BARLOW: Okay.</p> <p>8 BY MR. BARLOW:</p> <p>9 Q. Doctor, at the time of the launch of</p> <p>10 the TVT Exact, it was known to Ethicon that there</p> <p>11 could be foreign body response to the Exact that</p> <p>12 would result in inflammation, extrusion, erosion,</p> <p>13 exposure, and fistula formation; correct?</p> <p>14 A. Yes.</p> <p>15 Q. At the time of the launch of the TVT</p> <p>16 Exact, it was known to Ethicon that mesh extrusion,</p> <p>17 exposure, or erosion into the vagina or other</p> <p>18 structures or organs could result from the use of</p> <p>19 the TVT Exact.</p> <p>20 A. Yes.</p> <p>21 Q. It was known at the time of the</p> <p>22 launch of the TVT Exact that mesh extrusion,</p> <p>23 exposure, or erosion into the vagina or other</p> <p>24 structures or organs could result from the TVT</p> <p>25 Exact; correct?</p>

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<p>1 A. Yes.</p> <p>2 Q. It was known to Ethicon at the time</p> <p>3 of the launch of the TVT Exact that acute and/or</p> <p>4 chronic pain could result from the TVT Exact;</p> <p>5 correct?</p> <p>6 A. Yes.</p> <p>7 Q. It was known at the time of the</p> <p>8 launch of the TVT Exact that pain with intercourse,</p> <p>9 which in some patients may not resolve, could result</p> <p>10 from the use of the TVT Exact; correct?</p> <p>11 A. Yes.</p> <p>12 Q. It was also known by Ethicon that</p> <p>13 pain with intercourse, which in some patients may</p> <p>14 not resolve, could result from the TVT Exact sling</p> <p>15 itself; correct?</p> <p>16 A. Can you ask that again, please?</p> <p>17 Q. It was known at the time of the</p> <p>18 launch of the TVT Exact that pain with intercourse,</p> <p>19 which in some patients may not resolve, could result</p> <p>20 from the TVT Exact.</p> <p>21 A. From the use of TVT Exact in that</p> <p>22 procedure.</p> <p>23 Q. Okay.</p> <p>24 Doctor, with regard to the -- strike</p> <p>25 that.</p>	<p>1 treatment; correct?</p> <p>2 A. Correct.</p> <p>3 Q. It was known at the time of the</p> <p>4 launch of the TVT Exact that one or more revision</p> <p>5 surgeries may be necessary to treat adverse</p> <p>6 reactions from the TVT Exact; correct?</p> <p>7 A. From the use of the TVT Exact, yes.</p> <p>8 Q. Well, one or more revision surgeries</p> <p>9 may be necessary to treat adverse reactions that</p> <p>10 result from the Exact sling itself; correct?</p> <p>11 A. Yes.</p> <p>12 Q. And that was known at the time of its</p> <p>13 launch. Right?</p> <p>14 A. Yes.</p> <p>15 Q. Doctor, it was known by Ethicon at</p> <p>16 the time of the launch of the TVT Exact that in</p> <p>17 cases where the Prolene mesh needed to be removed in</p> <p>18 whole or in part, significant dissection may be</p> <p>19 required; correct?</p> <p>20 A. The whole part, yes. The part part,</p> <p>21 removed in part, may not require --</p> <p>22 Q. It depends on how big a part. Right?</p> <p>23 A. Well, that and where it -- from where</p> <p>24 it needs to be removed. If you'd like further</p> <p>25 explanation, I'd be happy to give it to you.</p>
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<p>1 It was known at the time of the</p> <p>2 launch of the TVT Exact that neuromuscular problems,</p> <p>3 including acute and/or chronic pain in the groin,</p> <p>4 thigh, leg, pelvic and abdominal area could occur</p> <p>5 with the TVT Exact; correct?</p> <p>6 A. No, there was no -- there was no</p> <p>7 thought that pain in the thigh or leg --</p> <p>8 Q. Is that because the TVT Exact is a</p> <p>9 retropubic approach?</p> <p>10 A. That's correct.</p> <p>11 Q. Okay.</p> <p>12 So let me ask it a different way:</p> <p>13 Doctor, with regard to -- strike that.</p> <p>14 It was known at the time of the</p> <p>15 launch of the TVT Exact that neuromuscular problems,</p> <p>16 including acute and/or chronic pain in the groin,</p> <p>17 pelvic and abdominal area could result from the TVT</p> <p>18 Exact; correct?</p> <p>19 A. From the use of the TVT Exact in that</p> <p>20 procedure, yes.</p> <p>21 Q. Okay.</p> <p>22 Doctor, it was known at the time of</p> <p>23 the launch of the TVT Exact that the adverse</p> <p>24 reactions that we've been discussing could -- that</p> <p>25 could result from the TVT Exact may require surgical</p>	<p>1 Q. Okay. What would be the distinction?</p> <p>2 A. Well, one of the times where part of</p> <p>3 the TVT Exact, or really any of the other TVTs,</p> <p>4 might need to be removed is if it is exposed in the</p> <p>5 vagina; and in that case, it doesn't require a</p> <p>6 dissection of any significance. It's something that</p> <p>7 can be done in the office with a scissors, where a</p> <p>8 small piece that's exposed is just removed.</p> <p>9 Q. And, Doctor, there are other -- and I</p> <p>10 need to object as nonresponsive except to the extent</p> <p>11 he was answering with regard to the Exact, because</p> <p>12 that's where our questions are -- that's what my</p> <p>13 questions are directed to.</p> <p>14 With regard to the TVT Exact, there</p> <p>15 may be repairs that need to -- removals that need to</p> <p>16 occur that go beyond just the -- a small exposure</p> <p>17 that can be done in office; correct?</p> <p>18 A. Correct.</p> <p>19 Q. And when those surgeries to remove</p> <p>20 portions of the TVT Exact go beyond just the portion</p> <p>21 that would be exposed -- small portion under the</p> <p>22 urethra, if it requires greater -- strike that.</p> <p>23 There are removals of TVT Exact mesh</p> <p>24 that require greater dissection when you don't</p> <p>25 remove the whole device; correct?</p>

19 (Pages 362 to 365)

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<p>1 A. That's correct.</p> <p>2 Q. In fact, it's very difficult to ever</p> <p>3 remove the entire device; correct?</p> <p>4 A. It's a difficult surgery, yes.</p> <p>5 Q. And so it would be true that when the</p> <p>6 Prolene mesh needs to be removed in part, if it's a</p> <p>7 significant part, significant dissection may be</p> <p>8 required; correct?</p> <p>9 A. That's correct.</p> <p>10 Q. And that was something that was known</p> <p>11 to Ethicon at the time of the launch of the TVT</p> <p>12 Exact; correct?</p> <p>13 A. Yes.</p> <p>14 Q. And that's why you used the language</p> <p>15 may be required as opposed to will be required.</p> <p>16 Right?</p> <p>17 A. That's correct.</p> <p>18 Q. Doctor, with regard to -- strike</p> <p>19 that.</p> <p>20 At the time of the launch of the TVT</p> <p>21 Exact, it was known that use of the Exact could</p> <p>22 result in de novo urge incontinence; correct?</p> <p>23 A. Yes.</p> <p>24 Q. At the time of the launch of the TVT</p> <p>25 Exact, it was known to Ethicon that implantation --</p>	<p>1 Q. At the time of the launch of the TVT</p> <p>2 Exact, it would have been reasonable to include in</p> <p>3 the adverse reactions that mesh exposure, extrusion,</p> <p>4 or erosion into the vagina or other structures or</p> <p>5 organs could occur; correct?</p> <p>6 A. Yes.</p> <p>7 Q. At the time of the launch of the TVT</p> <p>8 Exact, it would have been reasonable to list as a</p> <p>9 possible adverse reaction that acute and/or chronic</p> <p>10 pain could result; correct?</p> <p>11 A. Yes.</p> <p>12 Q. At the time of the launch of the TVT</p> <p>13 Exact, it would have been reasonable to list as an</p> <p>14 adverse reaction that pain with intercourse, which</p> <p>15 in some patients may not resolve, could result;</p> <p>16 correct?</p> <p>17 A. Yes.</p> <p>18 Q. At the time of the launch of the TVT</p> <p>19 Exact, it would have been reasonable to list as an</p> <p>20 adverse reaction that neuromuscular problems,</p> <p>21 including acute and/or chronic pain in the groin,</p> <p>22 pelvic and/or abdominal area could result; correct?</p> <p>23 A. Yes.</p> <p>24 Q. At the time of the launch of the TVT</p> <p>25 Exact, it would have been reasonable to list as a</p>
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<p>1 strike that.</p> <p>2 Doctor, at the time of the launch of</p> <p>3 the TVT Exact, it was known that a potential adverse</p> <p>4 reaction was de novo urinary frequency; correct?</p> <p>5 A. Yes.</p> <p>6 Q. At the time of the launch of the TVT</p> <p>7 Exact, it was known that a possible adverse reaction</p> <p>8 was de novo urinary retention; correct?</p> <p>9 A. Yes.</p> <p>10 Q. At the time of the launch of the TVT</p> <p>11 Exact, it was known by Ethicon that a possible</p> <p>12 adverse reaction was de novo urinary obstruction;</p> <p>13 correct?</p> <p>14 A. Yes.</p> <p>15 Q. At the time of the launch of the TVT</p> <p>16 Exact, it was known by Ethicon that a possible</p> <p>17 adverse reaction was de novo voiding dysfunction;</p> <p>18 correct?</p> <p>19 A. Yes.</p> <p>20 Q. Doctor, at the time of the launch of</p> <p>21 the TVT Exact, it would have been reasonable to warn</p> <p>22 that there could be foreign body response resulting</p> <p>23 in inflammation, extrusion, erosion, exposure, and</p> <p>24 fistula formation as an adverse reaction; correct?</p> <p>25 A. Yes.</p>	<p>1 possible adverse reaction -- strike that.</p> <p>2 At the time of the launch of the TVT</p> <p>3 Exact, it would have been reasonable to include that</p> <p>4 the adverse reactions of the Exact may require</p> <p>5 surgical treatment; correct?</p> <p>6 A. Yes.</p> <p>7 Q. At the time of the launch of the TVT</p> <p>8 Exact, it would have been reasonable to include in</p> <p>9 the IFU that one or more revision surgeries may be</p> <p>10 necessary to treat adverse reactions to the TVT</p> <p>11 Exact; correct?</p> <p>12 A. Yes.</p> <p>13 Q. At the time of the launch of the TVT</p> <p>14 Exact, it would have been reasonable to include in</p> <p>15 the adverse reactions in the IFU that in cases in</p> <p>16 which the Prolene mesh needs to be removed in part</p> <p>17 or whole, significant dissection may be required;</p> <p>18 correct?</p> <p>19 A. Yes.</p> <p>20 Q. At the time of the launch of the TVT</p> <p>21 Exact, it would have been reasonable to include in</p> <p>22 the adverse reactions section that de novo urge</p> <p>23 incontinence could occur; correct?</p> <p>24 A. Yes.</p> <p>25 Q. At the time of the launch of the TVT</p>

20 (Pages 366 to 369)

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<p>1 Exact, it would have been reasonable to include as a 2 possible adverse reaction that de novo urinary 3 frequency could occur; correct? 4 A. Yes. 5 Q. At the time of the launch of the TVT 6 Exact, it would have been reasonable to include in 7 the adverse reactions section that urinary retention 8 could occur; correct? 9 A. Yes. 10 Q. At the time of the launch of the TVT 11 Exact, it would have been reasonable to include in 12 the adverse reactions that urinary obstruction could 13 occur; correct? 14 A. Yes. 15 Q. And at the time of the launch of the 16 TVT Exact, it would have been reasonable to include 17 that de novo voiding dysfunction could occur; 18 correct? 19 A. Yes. 20 Q. Okay, Doctor. Turning to Exhibits 21 1661 and -- through 1664, Doctor, the TVT IFU for 22 Exact -- strike that. 23 MS. KABBASH: I think this is harder 24 than a normal deposition. 25 MR. BARLOW: It is. Yes, I can</p>	<p>1 vagina or other organs. 2 Q. Okay. 3 Doctor -- I'm going to object as 4 nonresponsive. 5 Doctor, the words mesh extrusion, 6 exposure, or erosion into the vagina or other 7 structures or organs does not appear in the adverse 8 reactions section of the TVT Exact IFU, does it? 9 A. Right. 10 MR. GAGE: Object to form. 11 THE WITNESS: The vagina and other 12 organs aren't spelled out, but the other words are 13 there. 14 MR. BARLOW: Object as nonresponsive. 15 What did I mess up, Bill? 16 MR. GAGE: You said -- when you said 17 "the words" and then you listed, if you said "the 18 phrase," it would not be objectionable, but because 19 some of the words appear and some don't, that's why 20 I objected. 21 MR. BARLOW: I understand. 22 BY MR. BARLOW: 23 Q. Doctor, the phrase mesh extrusion, 24 exposure, or erosion into the vagina or other 25 structures or organs does not appear in the TVT</p>
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<p>1 babble more fluently when I'm just asking regular 2 questions than kind of these formal questions, 3 but... 4 BY MR. BARLOW: 5 Q. Doctor, in the TVT Exact IFU, chronic 6 foreign body response resulting in inflammation, 7 extrusion, erosion, exposure, or fistula formation 8 is not listed; correct? 9 A. The word chronic is not mentioned. 10 Q. And to the extent foreign body 11 response is discussed at all, it is characterized as 12 being transitory; correct? 13 A. That's correct. 14 Q. And there is -- we know that there 15 can be a chronic foreign body response with the TVT 16 Exact; correct? 17 A. Histologically chronic. 18 Q. That's correct? 19 A. Yes. 20 Q. Doctor, the adverse reactions listed 21 in the TVT Exact IFU do not include mesh extrusion, 22 exposure, or erosion into the vagina or other 23 structures or organs, do they? 24 A. Well, it includes extrusion, erosion, 25 and fistula formation, but it doesn't specify the</p>	<p>1 Exact IFU, does it? 2 A. That's correct. 3 Q. It's not noted that the extrusion, 4 exposure, or erosion can be into the vagina or other 5 structures or organs; correct? 6 A. Correct. 7 Q. The TVT Exact IFU does not include a 8 warning regarding acute and/or chronic pain, does 9 it? 10 A. That's correct. 11 Q. Doctor, the TVT IFU -- Exact IFU does 12 not include a warning regarding pain with 13 intercourse, which in some patients may not resolve; 14 correct? 15 A. Correct. 16 Q. That's not listed in the adverse 17 reactions; correct? 18 A. That's correct. 19 Q. The TVT Exact IFU does not list 20 neuromuscular problems, including acute and/or 21 chronic pain in the groin, pelvis and/or abdominal 22 area, does it? 23 A. That's correct. 24 Q. The TVT Exact IFU does not include a 25 warning or information that adverse reactions to the</p>

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<p>1 Exact may require surgical treatment, does it?</p> <p>2 A. It does not.</p> <p>3 Q. The TVT Exact IFU does not include a</p> <p>4 statement or information that one or more revision</p> <p>5 surgeries may be necessary to treat the adverse</p> <p>6 reactions to the Exact, does it?</p> <p>7 A. It does not.</p> <p>8 Q. The TVT Exact IFU does not state that</p> <p>9 in cases in which the Prolene mesh needs to be</p> <p>10 removed in part or whole, that significant</p> <p>11 dissection may be required, does it?</p> <p>12 A. It does not.</p> <p>13 Q. And the TVT Exact IFU does not state</p> <p>14 that even when multiple surgery -- strike that.</p> <p>15 The TVT Exact IFU does not state that</p> <p>16 when one or more revision surgeries are performed,</p> <p>17 they may not resolve or cure the adverse reactions</p> <p>18 to the Exact; correct?</p> <p>19 A. Correct.</p> <p>20 Q. Doctor, the TVT Exact IFU does not</p> <p>21 state that de novo urge incontinence can result from</p> <p>22 the Exact, does it?</p> <p>23 MR. GAGE: Objection to the form.</p> <p>24 THE WITNESS: Actually, it does.</p> <p>25 MR. BARLOW: Okay.</p>	<p>1 that it extended past the TVT Exact, which was the</p> <p>2 subject of the question, but let me ask it this way.</p> <p>3 Doctor, urge incontinence is not</p> <p>4 included in the adverse reactions section of the TVT</p> <p>5 Exact IFU, does it?</p> <p>6 A. No.</p> <p>7 Q. Or is it. Yeah.</p> <p>8 With regard to the mention of</p> <p>9 detrusor instability in the warnings and precautions</p> <p>10 section, that is -- that warning is intended to make</p> <p>11 the surgeon aware of the possibility of de novo</p> <p>12 detrusor instability as a result of surgical</p> <p>13 technique; correct?</p> <p>14 A. There's a specific warning about</p> <p>15 implanting the Gynecare TVT Exact, but the sentence</p> <p>16 begins: As with other incontinence procedures, de</p> <p>17 novo detrusor instability may occur.</p> <p>18 Q. And that would -- and read as a</p> <p>19 whole, that's directed toward warning surgeons not</p> <p>20 to put the Exact in too tightly; correct?</p> <p>21 A. Well, but it also qualifies that this</p> <p>22 is a part of any incontinence surgery, whether or</p> <p>23 not the Exact is used or any other -- it's a general</p> <p>24 warning for incontinence procedures with some --</p> <p>25 with a specific warning of one thing they can do to</p>
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<p>1 THE WITNESS: And I really just</p> <p>2 discovered this looking at all these IFUs side by</p> <p>3 side, as you asked me to do; and I noticed that in</p> <p>4 warnings and precautions, there's a statement that</p> <p>5 says: As with other incontinence procedures, de</p> <p>6 novo detrusor instability, which is the medical term</p> <p>7 for urge incontinence, may occur following the</p> <p>8 Gynecare TVT Exact continence system procedure. To</p> <p>9 minimize this risk, make sure -- I can go on, but --</p> <p>10 MR. BARLOW: Make sure that -- go</p> <p>11 ahead. Finish the --</p> <p>12 THE WITNESS: Make sure to place the</p> <p>13 implant tension free in the mid-urethral position.</p> <p>14 MR. BARLOW: Okay.</p> <p>15 THE WITNESS: And, unfortunately,</p> <p>16 that's going to modify or amend many of the answers</p> <p>17 that I gave today and yesterday, because I just</p> <p>18 really found this. I was looking for the words urge</p> <p>19 incontinence, and detrusor instability just kind of</p> <p>20 went by and I just discovered it in reviewing these</p> <p>21 documents.</p> <p>22 MR. BARLOW: All right.</p> <p>23 BY MR. BARLOW:</p> <p>24 Q. Doctor, the -- let's do it this way</p> <p>25 -- I need to object as nonresponsive to the extent</p>	<p>1 try to avoid it with this procedure.</p> <p>2 Q. Okay.</p> <p>3 Doctor, with regard to urinary</p> <p>4 frequency, urinary frequency is not included in the</p> <p>5 adverse reactions section of the TVT Exact IFU, does</p> <p>6 it?</p> <p>7 A. No.</p> <p>8 Q. The TVT Exact IFU adverse reactions</p> <p>9 section does not include urinary retention, does it?</p> <p>10 A. Only in -- with reference to urinary</p> <p>11 tract obstruction.</p> <p>12 Q. The specific issue of urinary</p> <p>13 retention does not appear in the TVT Exact IFU</p> <p>14 adverse reactions section, does it?</p> <p>15 A. The words don't appear.</p> <p>16 Q. Okay.</p> <p>17 Urinary obstruction -- strike that.</p> <p>18 Doctor, the TVT Exact adverse</p> <p>19 reactions does not include urinary obstruction</p> <p>20 resulting from scarification of the TVT Exact, does</p> <p>21 it?</p> <p>22 A. Just check -- no.</p> <p>23 Q. Doctor, the TVT Exact IFU does not</p> <p>24 include voiding dysfunction as a result of the TVT</p> <p>25 Exact sling itself, does it?</p>

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<p>1 A. Those words are not included, but 2 voiding dysfunctions are discussed. 3 Q. There are other voiding -- there are 4 other voiding dysfunctions other than obstruction; 5 correct? 6 A. Right. Detrusor instability is 7 another one and that's in the warnings. 8 Q. Doctor, of the adverse reactions 9 listed on 1641, detrusor instability implicates 10 which of those? 11 A. Detrusor instability is included in 12 the IFU in the warnings and precautions section, not 13 in the adverse reactions section. 14 MR. BARLOW: Okay. I need to object 15 as nonresponsive. 16 BY MR. BARLOW: 17 Q. De novo detrusor instability 18 implicates which, if any, of the urinary adverse 19 reactions listed on 1641 -- Exhibit 1641? 20 MS. KABBASH: On the list. 21 MR. GAGE: He's asking about -- he's 22 wanting you to look at this list when you answer the 23 question. 24 THE WITNESS: Oh, I'm sorry. 25 MR. GAGE: So would you now --</p>	<p>1 MR. FREESE: I mean, I'm going to go 2 over -- 3 MR. GAGE: I mean, you know what I'm 4 talking about. 5 MR. FREESE: I'm going over an IFU. 6 MR. GAGE: Yep. 7 MR. BARLOW: At this time, I'm going 8 to -- sorry. At this time, I'm going to turn the 9 questioning over to Mr. Freese on behalf of the 10 Texas plaintiffs. 11 I just want to reiterate, and I'm not 12 going to go through the whole thing again, what we 13 talked about on the record yesterday: The MDL's 14 position is, is that due to the volume and manner in 15 which the discovery was produced, the document 16 discovery was produced, in advance of this 17 deposition, we've been unable to review large 18 portions, perhaps the majority, of those documents. 19 And we reserve our right, after we've 20 had an adequate opportunity to review those 21 documents, to come back and seek to question some 22 more in a nonduplicative manner. Okay? 23 With that, I'm going to turn it over 24 to Mr. Freese. We can go off the record. 25 THE VIDEO TECHNICIAN: Sure. The</p>
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<p>1 THE WITNESS: I misunderstood. 2 MR. GAGE: -- Alex, reask the 3 question? 4 THE WITNESS: Yeah. 5 BY MR. BARLOW: 6 Q. Doctor, detrusor instability 7 implicates which of the urinary conditions on 8 Exhibit 1641? 9 A. Urge incontinence. 10 Q. Is that the only one? 11 A. Yes. 12 Q. Okay. 13 A. Although some patients with detrusor 14 instability have urinary frequency, also. 15 Q. Because of the detrusor instability? 16 A. Yes. 17 MR. BARLOW: Doctor, give me just a 18 minute to fret, and then I'm probably going to turn 19 it over to Rich. 20 MR. GAGE: And, Rich, are you please 21 going to tell us you're not going to go through 22 IFUs? 23 MR. FREESE: I'm not going over IFUs, 24 I can tell you that. 25 MR. GAGE: Thank you.</p>	<p>1 time is 11:41. We're going off the record. 2 - - - 3 (A discussion off the record 4 occurred.) 5 - - - 6 THE VIDEO TECHNICIAN: The time is 7 11:45. We're back on the record. 8 - - - 9 EXAMINATION 10 - - - 11 BY MR. FREESE: 12 Q. Good morning, Dr. Weisberg. How are 13 you doing? 14 A. Good morning. 15 Q. I'm Richard Freese and we've met 16 before, have we not? 17 A. We have. 18 Q. I think this is maybe the -- either 19 the second or third time I've been in a deposition 20 with you. 21 I get the privilege of being cleanup 22 today, so that may encompass me jumping around a 23 little bit, so I'll apologize to you ahead of time, 24 but I'm going to try to cover what I need to 25 cover and then ask you some questions that relate to</p>

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<p>1 some that you may have already answered and -- so 2 just do your best to work with me, if you don't 3 mind. 4 A. Please proceed. 5 Q. Great. Thank you. 6 I want to first show you what is 7 being marked as Plaintiffs' Exhibit P-1665. 8 - - - 9 (Deposition Exhibit No. P-1665, 10 E-Mail Chain, ETH.MESH.17619387 through 11 ETH.MESH.17619398, was marked for 12 identification.) 13 - - - 14 BY MR. FREESE: 15 Q. And this is a series of e-mails 16 between Stacy Kluesner and Heather Rodriguez and 17 Richard Sedlatschek? Do you see that? 18 A. Sedlatschek. 19 Q. Sedlatschek -- do you see that -- 20 first of all, have you seen these series of e-mails 21 before, Dr. Weisberg? 22 A. Let me just take a quick look. 23 Q. Yes, sir. 24 MR. GAGE: You need to go to the back 25 to start from the front.</p>	<p>1 Counsel represented that it was on 2 the list of documents that were produced by Ethicon 3 in response to this deposition notice. We've 4 checked our list. It does, in fact, appear on the 5 list. 6 From my reading of the document, I 7 don't see how it pertains at all to the IFU drafts 8 or the changes that are the subject of the 9 deposition. 10 So I don't object to plaintiffs' 11 counsel asking him what, if any, relationship this 12 document has to the changes in the IFU, because he 13 may know something that I don't, but I will object 14 to further questioning if he answers and says "I 15 don't know what relationship this has to the IFU 16 changes" on the basis of the scope. 17 And I'll just limit my objection in 18 his presence to just saying, "Objection; beyond the 19 scope of the deposition." 20 MR. FREESE: Well, that's fine. Let 21 the record be clear, this is a document that was 22 within the avalanche of tens of thousands, if not 23 hundreds of thousands, of pages of documents that 24 were produced to us responsive to this deposition 25 notice.</p>
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<p>1 THE WITNESS: Yeah, yeah. 2 (Pause.) 3 THE WITNESS: I have seen them 4 before, but I'll need a few minutes to review all 5 the content. 6 MR. FREESE: Okay. 7 THE WITNESS: If you don't mind. 8 MR. FREESE: Well, if you need some 9 time, we can just -- we can jump off the record for 10 a second and let you look at it. 11 THE WITNESS: Yeah, just give me five 12 minutes. 13 MR. FREESE: Sure. 14 THE VIDEO TECHNICIAN: The time is 15 11:47. We're going off the record. 16 - - - 17 (A discussion off the record 18 occurred.) 19 - - - 20 (The following discussion off the 21 videotape record occurred: 22 MR. GAGE: All right. The witness 23 has left the room. I'm going to -- and counsel -- 24 plaintiffs' counsel has handed Dr. Weisberg an 25 e-mail chain Bates marked ETH.MESH.17619387.</p>	<p>1 Dr. Weisberg has been designated to 2 testify on behalf of the corporation on the -- on 3 issues related to the IFU. This is a document that 4 was produced in response to that. 5 Obviously, I'm entitled to ask the 6 witness about it. He's already admitted that he has 7 seen it and is aware of the document. We're going 8 to find out in what context he became aware of it. 9 But I would -- I would really ask, 10 William, that you say nothing other than form or 11 scope and leave it at that and not do any further, 12 you know, suggesting to the witness what the answer 13 should be. 14 And suggesting to him that he has no 15 idea what it has to do with the IFU is not going to 16 lessen any of the questions I have, so -- 17 MR. GAGE: And don't worry. That's 18 why I sent him out of the room, because I didn't 19 want him to hear that. 20 MR. BARLOW: I would add that on the 21 face of the document itself in the e-mail chain, 22 that it discusses how the content of the other 23 e-mails are going to be used in response to Health 24 Canada and their inquiries in question. 25 So I think on the face of the</p>

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<p>1 document, it's relevant to this deposition and 2 within the scope of this deposition. 3 MR. GAGE: Got it. So let's go get 4 Marty back in and let's see if he's read it and... 5 - - - 6 THE VIDEO TECHNICIAN: The time is 7 11:55. We're back on the record. 8 BY MR. FREESE: 9 Q. Dr. Weisberg, you have in front of 10 you Plaintiffs' Exhibit 1665; is that correct, sir? 11 A. Yes. 12 Q. And this is a series of e-mails from 13 various people within Ethicon and some folks that 14 work for a supplier of Ethicon; correct? 15 A. Yes. 16 Q. And you have seen this string of 17 e-mails before? 18 A. It looks familiar, but I can't 19 pinpoint when or how much detail I went into. 20 Q. Do you remember the last time you saw 21 this string of e-mails? 22 A. It was -- it was -- no, I don't. 23 Q. Okay. 24 A. I really don't. 25 Q. Did you look at it in preparation for</p>	<p>1 Q. And have done so for many, many 2 years; correct? 3 A. Yes. 4 Q. And were you aware in December of 5 2013 of the e-mail that Jacqueline Ferro from Secant 6 sent to Lea Ann Conway, Jeff Robertson regarding the 7 Secant Medical inquiry on Gynecare mesh products? 8 A. Although I wasn't involved in this 9 particular issue at the time, I do remember hearing 10 about it. 11 Q. Okay. And the issue you heard about 12 was that your supplier was concerned about the 13 complications and alleged injuries occurring from 14 the use of their Prolene mesh and lawsuits resulting 15 therefrom; correct? 16 A. That's -- 17 MR. GAGE: Object to form. 18 THE WITNESS: That's correct. 19 BY MR. FREESE: 20 Q. And wanted Johnson & Johnson to 21 answer some questions to satisfy them regarding the 22 concerns that Secant and its insurers had; is that 23 correct? 24 A. That's correct. 25 Q. Tell me just generally what you</p>
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<p>1 your deposition today? 2 A. I don't believe that I saw this 3 particular e-mail. 4 Q. You understand, sir, that this 5 document was produced to us as responsive to our 6 request for all documents related to the topics of 7 which you've been designated by the company to 8 testify for. Okay? 9 A. I understand that. 10 Q. I'm just trying to give you some 11 context there. 12 Sir, do you know what Secant Medical 13 is? 14 A. Yes. 15 Q. And would you tell us what Secant 16 Medical is, sir? 17 A. It's a manufacturer of mesh. 18 Q. And is it, in fact, the manufacturer 19 of the Prolene polypropylene mesh that is used in 20 all of Johnson & Johnson's TVT products? 21 A. I'm not sure if they're the exclusive 22 supplier. 23 Q. They certainly supply Prolene 24 polypropylene mesh for use in TVT. Am I correct? 25 A. Yes, they do.</p>	<p>1 remember about the issue, and then I'm going to ask 2 you some specific questions. 3 A. That is pretty much -- 4 MR. FREESE: Objection; beyond the 5 scope. 6 THE WITNESS: That is pretty much it. 7 This was a project that I wasn't personally involved 8 in. There was another -- other medical directors 9 attending to this project, but it's -- I remember 10 hearing it. 11 BY MR. BARLOW: 12 Q. Was this considered a major issue? 13 MR. GAGE: Objection; scope. 14 THE WITNESS: I -- I can't tell you 15 how it was viewed. I think we take everything very 16 seriously. 17 BY MR. FREESE: 18 Q. Who was the other medical director 19 that was involved with this Secant issue? 20 MR. GAGE: Objection; scope. 21 THE WITNESS: I believe it was Piet 22 Hinoul. 23 BY MR. FREESE: 24 Q. And how do you know that? 25 MR. GAGE: Objection; scope.</p>

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<p>1 THE WITNESS: That's -- in my 2 recollection, it was a discussion that we had, but 3 -- 4 BY MR. FREESE: 5 Q. When? 6 A. -- but I -- I can't pinpoint that. 7 I'm not even sure. This is a fuzzy memory. I knew 8 that I knew about it. It was a time that Piet was 9 managing these things. 10 That's the best I can do. 11 Q. Yes, sir. 12 Do you recall whether or not anyone 13 other than Secant in December of 2013 was supplying 14 Johnson & Johnson with Prolene polypropylene mesh 15 for use in TVT products? 16 A. I don't know the answer to that. 17 MR. GAGE: Objection; scope. 18 THE WITNESS: I don't know the answer 19 to that. 20 BY MR. FREESE: 21 Q. As you sit here today, can you name 22 me another one other than Secant? 23 MR. GAGE: Objection; scope. 24 THE WITNESS: I cannot. 25 BY MR. FREESE:</p>	<p>1 are double-sided. I'm sorry. 2 MR. GAGE: Last page of the e-mail 3 chain is what he meant to say. 4 MR. FREESE: I'm sorry. Last page of 5 the e-mail chain. Thank you. 6 THE WITNESS: Okay. 7 BY MR. FREESE: 8 Q. Do you see Ms. Conway's e-mail? 9 MR. GAGE: Object to scope. 10 THE WITNESS: Yes, I do. Yes, I do. 11 MR. FREESE: And, William, I'll give 12 you a standing objection on scope on this exhibit if 13 you want. 14 MR. GAGE: Yes, I would. 15 MR. FREESE: That's fine. 16 MR. GAGE: Is that acceptable to MDL 17 counsel as well? 18 MR. BARLOW: Yes. 19 MR. GAGE: Okay. 20 BY MR. FREESE: 21 Q. She goes on -- first of all, who is 22 Lea Ann Conway? 23 A. I'm trying to think of Lea Ann's 24 position at that time. I believe she was in our 25 quality division, but I'm not sure of her particular</p>
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<p>1 Q. You could name Secant, could you not? 2 MR. GAGE: Objection; scope. 3 THE WITNESS: I knew about Secant. 4 BY MR. FREESE: 5 Q. You knew that Secant was a supplier 6 to J & J for its TVT Prolene polypropylene mesh. 7 MR. GAGE: Objection; scope. 8 THE WITNESS: I knew that they 9 supplied mesh and I wasn't any more -- I didn't know 10 anything more specific than that. 11 BY MR. FREESE: 12 Q. And you see in the December 17th, 13 2013 e-mail, Ms. Conway writes: As you know, Secant 14 Medical supplies Prolene mesh for your vaginal and 15 uterine prolapse devices under the Gynecare TVT 16 line; is that correct? 17 MR. GAGE: Objection; scope. He 18 wasn't following you. I think he was reading that 19 sentence to you. Rich, you may want to re -- 20 THE WITNESS: Okay. I see. 21 MR. FREESE: I'm on the very last 22 page of the exhibit, Dr. Weisberg. 23 THE WITNESS: The last page of the 24 exhibit? 25 MR. BARLOW: Yeah, where Ms. -- mine</p>	<p>1 job. 2 Q. All right. Have you had occasion to 3 work with her? 4 A. Yes, and, you know, over the years, 5 people change their -- you know what? I'm not sure 6 what her position was at that time. 7 Q. Obviously, she was somebody at 8 Johnson & Johnson who worked with Secant. 9 A. Yes. 10 Q. All right. 11 A. Or had a relationship of some kind. 12 Q. Ms. Ferro says: Quote, Most 13 recently, in light of all the litigation around mesh 14 products used for vaginal and uterine prolapse, it 15 appears that the Biomaterials Assurance Act lacks 16 precedence and may not protect suppliers like Secant 17 as intended. 18 Do you see that? 19 A. Yes. 20 Q. Secant Medical is owned by Fenner 21 PLC, a public industrial company based in the UK, do 22 you see that? 23 A. Yes. 24 Q. Because our parent company is not in 25 the life science industry -- life sciences</p>

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<p>1 industry -- our insurance carriers are starting to 2 mandate that we no longer sell mesh for device 3 applications as outlined under the litigation. 4 Do you see that? 5 A. Yes. 6 Q. Is that the fact that you became 7 aware of at some point, through Dr. Hinoul or 8 someone else, that your supplier of Prolene mesh was 9 being instructed by their insurers not to supply 10 Johnson & Johnson with Prolene mesh for use in 11 vaginal and uterine prolapse devices? 12 MR. GAGE: Object to form. 13 THE WITNESS: Well, pretty much the 14 only thing I remember is that -- that Secant was 15 considering not supplying mesh anymore. That's -- 16 that's pretty much the sum total of this 17 interaction. 18 MR. FREESE: Yes, sir. 19 BY MR. FREESE: 20 Q. And it says -- goes on, quote, There 21 is also considerable discussion of this at our CEO 22 and board of directors level. It says BOD. Right? 23 A. Yes. 24 Q. She goes on to ask, quote, Is it 25 possible for you or a member in your organization to</p>	<p>1 Q. Essentially, Ms. Ferro's asking for 2 Johnson & Johnson to provide some insight into all 3 the changes that you had made, your company had 4 made, to the IFU user training and protocols to 5 solve or minimize the risk from litigation arising 6 out of the use of Prolene mesh; correct? 7 A. You can get that out of the letter, 8 yes. 9 Q. All right. 10 And the Prolene mesh that she's 11 referring to is the same Prolene mesh that is in all 12 TVT products; correct? 13 A. Yes, the mesh is the same. 14 Q. Now, do you know who -- and I'm going 15 to mispronounce the name -- Rick Sedlatschek is? 16 A. Sedlatschek? 17 Q. Sedlatschek. Thank you. 18 A. Yes. 19 Q. And he at the time was a vice 20 president of quality and regulatory compliance? 21 A. Yes. 22 Q. Did you work with him? 23 A. On occasion. 24 Q. And he prepared a rather lengthy 25 response to Secant to convince Secant to continue to</p>
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<p>1 share information on the rationale for keeping these 2 products on the market? Since the initial launch, I 3 am certain that there has been corrective action for 4 complaints and MDRs which resulted in changes to the 5 IFU, user training, protocols for care after 6 implantation, and design changes. 7 Do you see that? 8 A. Yes. 9 Q. Are you aware, Dr. Weisberg, whether 10 or not since the initial launch there were any 11 changes made by Johnson & Johnson or Ethicon in its 12 IFUs because of lawsuits that were filed against it? 13 MR. GAGE: Object to form. 14 THE WITNESS: Because of, no. 15 BY MR. FREESE: 16 Q. Would your answer be, during that 17 time, there were changes that we've discussed over 18 the last couple of days? 19 A. Yes. 20 Q. Was there any changes in user 21 training that Ethicon did since the filing of the 22 lawsuits against the company? 23 A. They're constantly updating their 24 training. I'm really not sure what changes would 25 have been made when.</p>	<p>1 sell Prolene mesh to Johnson & Johnson and Ethicon; 2 correct? 3 MR. GAGE: Objection to form. 4 THE WITNESS: Well, he prepared a 5 response to answer their questions. 6 BY MR. FREESE: 7 Q. And their question was, what have you 8 done in response to this litigation, because our 9 insurers are telling us they don't want us to sell 10 you Prolene mesh anymore for use in your vaginal and 11 pelvic products; correct? 12 MR. GAGE: Object to form. 13 THE WITNESS: Yes -- well, they said 14 they're starting to tell us. 15 MR. FREESE: Starting to mandate. 16 THE WITNESS: Starting to mandate, 17 yeah. 18 BY MR. FREESE: 19 Q. That they no longer sell mesh to 20 Johnson & Johnson. 21 A. Right. 22 Q. And this gentleman then writes his 23 response to Secant, explaining all of the reasons 24 why Johnson & Johnson believed that it was a safe 25 product; correct?</p>

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<p>1 MR. GAGE: Object to form.</p> <p>2 THE WITNESS: I mean, you said "all</p> <p>3 of the reasons." I'm not going to say that this is</p> <p>4 entirely inclusive of everything that could be said,</p> <p>5 but I think he responded to their questions.</p> <p>6 BY MR. FREESE:</p> <p>7 Q. If you'll look on what's the third</p> <p>8 page of Mr. --</p> <p>9 A. Sedlatschek's?</p> <p>10 Q. Sedlatschek. Thank you. I'm sorry</p> <p>11 -- Mr. Sedlatschek's e-mail, he quotes Dr. Nilsson's</p> <p>12 17-year follow-up study in support of the safety and</p> <p>13 efficacy of the Prolene mesh?</p> <p>14 A. Yes.</p> <p>15 Q. Nowhere does he tell Secant that Dr.</p> <p>16 Nilsson was a paid consultant for Ethicon, does he?</p> <p>17 A. No, not in this letter.</p> <p>18 Q. He goes on to say that in December of</p> <p>19 2013, Ethicon conducted a Quality Review Board with</p> <p>20 its most senior medical affairs, legal, regulatory,</p> <p>21 and quality leaders to assess the increased trend of</p> <p>22 litigation alleging injuries related to pelvic floor</p> <p>23 repair systems and Gynecare tension-free tape, as</p> <p>24 well as Prolene polypropylene mesh, Mersilene mesh,</p> <p>25 and UltraPro mesh and hernia repair meshes.</p>	<p>1 A. I see it, yes.</p> <p>2 Q. Assessing the increased trend in</p> <p>3 litigation alleging injuries, do you see that?</p> <p>4 A. Yes.</p> <p>5 Q. Were you involved in that Quality</p> <p>6 Review Board?</p> <p>7 A. I was not.</p> <p>8 Q. Who was the most senior medical</p> <p>9 affairs people in December of 2013 involved in that</p> <p>10 medical affairs -- I'm sorry. Let me start over.</p> <p>11 Who was the medical affairs doctor</p> <p>12 involved in the Quality Review Board in December of</p> <p>13 2013?</p> <p>14 A. I can't tell you for a fact, but it</p> <p>15 was likely Piet Hinoul.</p> <p>16 Q. Was there a report prepared out of</p> <p>17 that Quality Review Board?</p> <p>18 A. Typically, quality review boards do</p> <p>19 publish minutes.</p> <p>20 Q. Have you looked at those minutes,</p> <p>21 sir?</p> <p>22 A. I don't believe that I did.</p> <p>23 Q. And you said you were not part of</p> <p>24 that Quality Review Board.</p> <p>25 A. I was not.</p>
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<p>1 Do you see that?</p> <p>2 A. Yes, but I have to go back and amend</p> <p>3 my last answer.</p> <p>4 Q. Okay.</p> <p>5 A. Because on the attachment to this</p> <p>6 letter that Dr. Sedlatschek sent was a paper by</p> <p>7 Nilsson, and it said "Conflicts of Interest" on the</p> <p>8 last page. It says, "CGN," which is Nilsson "and CF</p> <p>9 have acted as consultants for Astellas, Ethicon, and</p> <p>10 Pfizer."</p> <p>11 Q. All right. And my question to you,</p> <p>12 sir, was -- was, did Mr. Sedlatschek say that in his</p> <p>13 e-mail?</p> <p>14 A. No, just in the attachment.</p> <p>15 I'm sorry. I lost your last question</p> <p>16 entirely.</p> <p>17 Q. Sure, that's okay. I was asking you</p> <p>18 where he's telling Secant in December of 2013</p> <p>19 Ethicon conducted a Quality Review Board.</p> <p>20 A. Okay.</p> <p>21 Q. Do you see that?</p> <p>22 A. And which page is that?</p> <p>23 Q. It's right under --</p> <p>24 A. I see it.</p> <p>25 Q. -- the Nilsson comment.</p>	<p>1 Q. He goes on to say: In addition to</p> <p>2 its own analysis, independent professional</p> <p>3 organizations have reaffirmed the safety and</p> <p>4 efficacy of polypropylene mesh mid-urethral slings</p> <p>5 such as TVT line of products.</p> <p>6 And then it goes on to say: For</p> <p>7 example, in a 2014 position statement, the American</p> <p>8 Urogynecologic Society and the Society of</p> <p>9 Urodynamics -- that's AUGS and SUFU; correct?</p> <p>10 A. Yes.</p> <p>11 Q. -- and he quotes from that position</p> <p>12 paper; correct?</p> <p>13 A. Yes.</p> <p>14 Q. And do you see where he calls that an</p> <p>15 independent professional organization?</p> <p>16 A. Yes.</p> <p>17 Q. Do you know who authored that</p> <p>18 position paper?</p> <p>19 A. I don't recall.</p> <p>20 Q. Do you know Charles Nager?</p> <p>21 A. Yes.</p> <p>22 Q. Do you know Dennis Miller?</p> <p>23 A. Yes.</p> <p>24 Q. Do you know Eric Rovner?</p> <p>25 A. Yes.</p>

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<p>1 Q. Do you know Paul Tulinkangas?</p> <p>2 A. Not personally.</p> <p>3 Q. Do you know he was one of the authors</p> <p>4 of the paper?</p> <p>5 A. I --</p> <p>6 Q. And do you know Dr. Goldman from</p> <p>7 Cleveland Clinic?</p> <p>8 A. Yes.</p> <p>9 Q. Did you know every one of those</p> <p>10 authors -- first of all, did you know that those</p> <p>11 were all the authors of the AUGS and SUFU position</p> <p>12 paper?</p> <p>13 A. I didn't recall who authored them.</p> <p>14 Q. Well, I'm going to represent to you</p> <p>15 those are all the authors, and every one of them are</p> <p>16 paid consultants either to Ethicon, American Medical</p> <p>17 Systems, or Boston Scientific Corporation.</p> <p>18 Did you know that?</p> <p>19 A. I was aware that some of them were</p> <p>20 consultants for us.</p> <p>21 Q. Well -- some were consultants for</p> <p>22 you, but every one of them were consultants for</p> <p>23 either you or your competitors.</p> <p>24 MR. GAGE: Object to form.</p> <p>25 BY MR. FREESE:</p>	<p>1 Q. I understand that, but Johnson &</p> <p>2 Johnson has very thorough rules and regulations</p> <p>3 governing your investigators to avoid appearance of</p> <p>4 bias, correct, in studies you did -- clinical trials</p> <p>5 you did?</p> <p>6 A. Well, I mean, we tell it like it is.</p> <p>7 You know, if it appears biased and it's not, then</p> <p>8 it's not biased.</p> <p>9 Q. In fact, Johnson & Johnson doesn't</p> <p>10 allow anymore its investigators of clinical studies</p> <p>11 to have an economic stake in the outcome of the</p> <p>12 data, do they?</p> <p>13 A. I don't know that that was the policy</p> <p>14 in 2013.</p> <p>15 Q. Well, I'll represent to you it was --</p> <p>16 as of 2010, it was the policy of Johnson & Johnson.</p> <p>17 A. Oh.</p> <p>18 Q. But my question is, the gentleman</p> <p>19 here on behalf of Ethicon is telling Secant that</p> <p>20 these are independent professional organizations,</p> <p>21 but he does not tell him or tell Secant that the</p> <p>22 authors of these position papers are all paid-for</p> <p>23 consultants by industry, does he?</p> <p>24 MR. GAGE: Object to form.</p> <p>25 THE WITNESS: No, that's not in</p>
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<p>1 Q. Did you know that?</p> <p>2 A. I wasn't sure of that, no.</p> <p>3 Q. It doesn't make them very</p> <p>4 independent, does it?</p> <p>5 MR. GAGE: Object to form.</p> <p>6 THE WITNESS: Pardon me?</p> <p>7 MR. GAGE: No --</p> <p>8 THE WITNESS: Oh. I think that these</p> <p>9 are ethical people who gave ethical answers based on</p> <p>10 their clinical experience, and they're honest and</p> <p>11 the organizations that they work for are concerned</p> <p>12 about women's health.</p> <p>13 MR. FREESE: Move to strike.</p> <p>14 Doctor, that really wasn't my</p> <p>15 question.</p> <p>16 BY MR. FREESE:</p> <p>17 Q. As paid consultants for Ethicon and</p> <p>18 Boston Scientific Corporation and American Medical</p> <p>19 Systems, there might be an appearance of bias if</p> <p>20 they are writing position papers saying that the</p> <p>21 industries that they're being paid by are making</p> <p>22 products that are safe and effective.</p> <p>23 You'd agree with me?</p> <p>24 A. No -- yeah, an appearance of bias,</p> <p>25 but an appearance of bias is not necessarily bias.</p>	<p>1 there.</p> <p>2 BY MR. FREESE:</p> <p>3 Q. And as you sit here today, you've not</p> <p>4 reviewed any of the results of that Quality Review</p> <p>5 Board.</p> <p>6 A. If I did, I don't recall.</p> <p>7 Q. Now, if you'll look up to the next</p> <p>8 e-mail above that --</p> <p>9 A. Date, please?</p> <p>10 Q. Yes, March 26th, 2014 --</p> <p>11 A. Okay.</p> <p>12 Q. -- written to Adrienne Brott -- do</p> <p>13 you know her?</p> <p>14 A. Not -- yes, I know who she is.</p> <p>15 Q. And who is she?</p> <p>16 A. See -- I believe she was -- she was</p> <p>17 with quality, too, but I'm not sure.</p> <p>18 Q. And Mr. Sedlatschek writes: The</p> <p>19 outline below is a response I had sent to Secant</p> <p>20 Medical in response to their request. I recommend</p> <p>21 you leverage it as much as possible in support of</p> <p>22 our response to Health Canada regarding similar</p> <p>23 questions and concerns. This info was reviewed and</p> <p>24 approved by all necessary Ethicon/J & J parties, so</p> <p>25 it is well vetted.</p>

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<p>1 Do you see that?</p> <p>2 A. Yes.</p> <p>3 Q. What does that mean?</p> <p>4 A. It means that it's accurate.</p> <p>5 Q. What does it mean to leverage as much</p> <p>6 as possible in support of our response to Health</p> <p>7 Canada?</p> <p>8 A. Well, Mr. Sedlatschek put a lot of</p> <p>9 work into that and has a lot of statistics and a lot</p> <p>10 of facts that are in there; and rather than</p> <p>11 reinventing the wheel, if the questions are the</p> <p>12 same, we know that we have a well-vetted document</p> <p>13 from which we can take information without having to</p> <p>14 go back to the files.</p> <p>15 Q. And he was telling Ms. Brott to use</p> <p>16 this information that he sent to Secant in</p> <p>17 leveraging their response to Health Canada.</p> <p>18 MR. GAGE: Object to form.</p> <p>19 THE WITNESS: Well, as I said, I am</p> <p>20 interpreting leveraging the way I think it was</p> <p>21 intended, and that means that here are answers that</p> <p>22 we researched and validated, use these to answer any</p> <p>23 other questions that Secant may ask.</p> <p>24 MR. FREESE: That's my question.</p> <p>25 BY MR. FREESE:</p>	<p>1 any of the Health Canada meetings. This may have</p> <p>2 been a behind-the-scenes, you know, somebody's</p> <p>3 working to get an answer to this question. They may</p> <p>4 have pulled it out of there. They may have pulled</p> <p>5 it out of, you know, any previous vetted, accurate</p> <p>6 answers.</p> <p>7 Q. Did you -- did you vet any of the</p> <p>8 responses that went to Health Canada, sir?</p> <p>9 A. They were all vetted.</p> <p>10 Q. By you?</p> <p>11 A. Yes.</p> <p>12 Q. And who else?</p> <p>13 A. Oh, I suspect that -- well, I can</p> <p>14 tell you the team, because everybody looked at them,</p> <p>15 and I think I have a list of the Health Canada team.</p> <p>16 These are just...</p> <p>17 (Pause.)</p> <p>18 THE WITNESS: Do I have a list of the</p> <p>19 Health Canada team. I have a list of the people who</p> <p>20 participated in changing of the IFU, but I don't</p> <p>21 have a list of the people on the Health Canada team.</p> <p>22 MR. FREESE: Let's go ahead and mark</p> <p>23 that as an exhibit so we'll have that.</p> <p>24 THE WITNESS: Okay.</p> <p>25 MR. FREESE: Has it already been</p>
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<p>1 Q. He's telling her to use this Secant</p> <p>2 response in responding to Health Canada if they ask</p> <p>3 similar questions --</p> <p>4 A. Yes.</p> <p>5 Q. -- about the product; correct?</p> <p>6 A. Yes.</p> <p>7 Q. And you were involved in the Health</p> <p>8 Canada project, were you not?</p> <p>9 A. I was.</p> <p>10 Q. That's why you're the spokesman for</p> <p>11 the company today; correct?</p> <p>12 MR. GAGE: Object to form.</p> <p>13 THE WITNESS: I don't know the second</p> <p>14 answer, but the first answer is, yes, I was involved</p> <p>15 in it.</p> <p>16 MR. FREESE: And you know you're here</p> <p>17 today to speak on behalf of the corporation on the</p> <p>18 Health Canada issues; correct?</p> <p>19 THE WITNESS: Yes.</p> <p>20 BY MR. FREESE:</p> <p>21 Q. And here's a document that is being</p> <p>22 recommended to use in the Health Canada response.</p> <p>23 A. Yes.</p> <p>24 Q. Did you know that?</p> <p>25 A. I didn't see this at all in the -- in</p>	<p>1 marked or --</p> <p>2 MR. KABBASH: No.</p> <p>3 MR. GAGE: No.</p> <p>4 MR. FREESE: I'm sure Mr. Gage won't</p> <p>5 mind. He's probably got a thousand of these sitting</p> <p>6 around somewhere.</p> <p>7 - - -</p> <p>8 (Deposition Exhibit No. P-1666,</p> <p>9 Document Labeled "Ethicon Approvers of</p> <p>10 2015 Pelvic Mesh IFU Changes", was marked</p> <p>11 for identification.)</p> <p>12 - - -</p> <p>13 BY MR. FREESE:</p> <p>14 Q. And P-1666 is entitled "Ethicon</p> <p>15 Approvers of 2015 Pelvic Mesh IFU Changes"?</p> <p>16 A. Yes.</p> <p>17 Q. You're obviously on there; correct?</p> <p>18 A. Yes.</p> <p>19 Q. Stacy Kluesner in regulatory affairs</p> <p>20 is on there; correct?</p> <p>21 A. Yes.</p> <p>22 Q. And, in fact, she's on the e-mail</p> <p>23 chain with Sedlatschek and Brott over this Secant</p> <p>24 response, is she not?</p> <p>25 A. Yes, she is.</p>

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<p>1 Q. And you said there was a Health 2 Canada team -- was that a distinct group of people 3 known as the Health Canada team? 4 A. Yeah, and many of those -- they may 5 be on that list, but the -- there was -- there were 6 Health Canada meetings on a regular basis from the 7 time we got the initial letter until the time that 8 Health Canada said that the situation was resolved. 9 Closed, I think, was their words. 10 Q. And -- 11 A. Now, I'm -- let me back that off. 12 That may have been the FDA that said it was closed. 13 There was a Health Canada team that 14 started when we got the initial letter until we 15 submitted our response and then for a little bit 16 after that. 17 Q. And it may have included more than 18 what's on Exhibit 1666? 19 A. That's correct. 20 Q. Do you believe there's a document 21 somewhere identifying everyone who's on the Health 22 Canada team? 23 A. I'm sure there is. 24 Q. You just don't have it with you -- 25 A. I just didn't pull that out. I</p>	<p>1 of those individuals. I believe they might have 2 been discussed with Adam yesterday. 3 MR. FREESE: Okay. 4 MS. KABBASH: But I don't know that 5 we have seen minutes beyond those Quality Review 6 Board meeting -- 7 MR. GAGE: It may be there. 8 MS. KABBASH: They may be there -- 9 MR. GAGE: But we just haven't seen 10 them. 11 MR. FREESE: Do you have an exemplar 12 -- 13 THE WITNESS: I don't. I mean, my 14 computer was swept, so every meeting invitation that 15 said Health Canada on it was pulled and provided. 16 MR. FREESE: Okay. 17 BY MR. FREESE: 18 Q. Dr. Weisberg, you said all the 19 communications with Health Canada were thoroughly 20 vetted by yourself and other members of the Health 21 Canada team? 22 A. Yes. 23 Q. Did anybody tell Health Canada that 24 your possibly sole supplier of polypropylene mesh 25 was threatening to stop selling it to you because it</p>
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<p>1 pulled out a couple of things that I knew I wouldn't 2 remember, lists of people, and that just wasn't a 3 list of the people. 4 Q. But it is a discrete document you 5 looked at in preparation for your deposition. 6 A. No, but I looked at a series of 7 e-mails and minutes from -- from the Health Canada 8 team meetings and if you look up at the top, you can 9 see who is addressed and those would be the people. 10 MR. FREESE: I don't know if we have 11 seen those yet. I don't have the Health Canada 12 minute meetings, not to say they're not in the 13 300,000 pages that were produced -- 14 MR. GAGE: They're in there. 15 THE WITNESS: Even in the meeting 16 invitations, their names would be in there. 17 MR. FREESE: Oh, that's fine. 18 MR. GAGE: Hang on a second, Rich. 19 (Pause.) 20 MR. GAGE: Rich, let Maha -- 21 MS. KABBASH: The only minutes that 22 I'm aware of that exist, Rich -- I'm not going to 23 say none exist, but what we have seen is the minutes 24 from the Quality Review Board meetings held in June 25 and August 2014. And Dr. Weisberg does have a list</p>	<p>1 was concerned about safety matters and the use of 2 its products for permanent implantation in women? 3 MR. GAGE: Object to form. 4 THE WITNESS: I don't believe so. 5 BY MR. FREESE: 6 Q. Did you ever suggest that might be a 7 prudent thing to do? 8 A. That's something that our regulatory 9 and legal people would probably address better than 10 I. 11 Q. And as you sit here today, you know 12 that nobody in regulatory alerted Health Canada 13 during this whole IFU discussion with Health Canada 14 that your either major or sole supplier of 15 polypropylene mesh was threatening to -- refusing to 16 even sell you the product anymore because of safety 17 concerns; correct? 18 MR. GAGE: Object to form. 19 THE WITNESS: I'm not aware of that. 20 BY MR. FREESE: 21 Q. Do you believe that that would have 22 been a prudent piece of information that Health 23 Canada might have considered relevant in its 24 assessment of your IFU? 25 MR. GAGE: Object to form.</p>

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<p>1 THE WITNESS: Well, I think if they 2 stopped selling it to us, that it would be prudent; 3 but they wanted to discuss with us about whether to 4 sell it to us or not, I don't know that that's -- 5 that would be prudent. 6 BY MR. FREESE: 7 Q. Okay. Well, how about if the reason 8 they were discussing refusing to sell it to you was 9 because of fears of injuries that were being caused 10 by women using the product? 11 MR. GAGE: Object to form. 12 BY MR. FREESE: 13 Q. Do you think that would have been a 14 relevant piece of information to share with the 15 officials at Health Canada? 16 MR. GAGE: Object to form. 17 THE WITNESS: No. I think that once 18 a result was -- was -- once there was a conclusion 19 to their inquiries, then it may have been important 20 to tell them. 21 BY MR. FREESE: 22 Q. It may have been important to tell 23 Health Canada. 24 A. Yes. 25 Q. But they never got told, did they?</p>	<p>1 Q. Could you answer my question? I can 2 have the court reporter read it back if you need to. 3 A. I -- I don't know where the line 4 stops about what needed to be transmitted to them 5 and what didn't and -- 6 Q. Well, let's break it down then. Did 7 all of your responses to Health Canada need to be 8 fully truthful and open and honest? 9 A. Yes. 10 Q. And the supplier of your 11 polypropylene mesh was questioning whether or not 12 they should even continue to sell you the mesh 13 anymore; correct? 14 A. No, they were alerting us that they 15 may be mandated to not sell it to us, may be. 16 Q. And if they stopped selling you mesh, 17 that would have necessitated you stop making your 18 slings; correct? 19 MR. GAGE: Object to form. 20 THE WITNESS: I'm not familiar enough 21 with our operations people to know whether they had 22 another supplier. 23 BY MR. FREESE: 24 Q. Well, can we agree that Secant 25 refusing to sell you polypropylene mesh would have</p>
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<p>1 A. Well, that's because there was no 2 change in what was being supplied to us. 3 Q. Well, they couldn't comment on 4 something they weren't told and they didn't know, 5 could they? 6 MR. GAGE: Object to form. 7 THE WITNESS: This question is -- is 8 strictly a legal and regulatory question; and 9 although I am representing the company, I was not 10 involved in any discussions about whether or not to 11 include that information. 12 BY MR. FREESE: 13 Q. Well, but you were on the team that 14 was vetting all the information that was going to 15 Health Canada; correct? 16 A. We vetted the information that was -- 17 that we drafted. 18 Q. You wanted to give Health Canada a 19 full and complete and honest appraisal of the 20 situation as it existed in 2014 when you were having 21 these discussions with Health Canada; correct? 22 MR. GAGE: Object to form. 23 THE WITNESS: We needed to answer 24 Health Canada's questions. 25 BY MR. FREESE:</p>	<p>1 been a major disruption to your manufacturing 2 process? 3 MR. GAGE: Object to form. 4 THE WITNESS: If that happened, which 5 it didn't. 6 MR. FREESE: I understand. 7 BY MR. FREESE: 8 Q. And during that time that you were 9 dealing with Health Canada, you had already been in 10 discussions for many months with Secant where they 11 were expressing the concern over the safety of the 12 use of mesh in vaginal and pelvic floor products; 13 correct? 14 MR. GAGE: Object to form. 15 THE WITNESS: Yes. 16 BY MR. FREESE: 17 Q. And someone at Ethicon made the 18 decision not to share that information with Health 19 Canada; correct? 20 MR. GAGE: Object to form. 21 THE WITNESS: I don't know if it was 22 even brought up and a decision was made or it was 23 just considered nothing that we needed to consider. 24 BY MR. FREESE: 25 Q. You certainly did not suggest telling</p>

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<p>1 Health Canada about what Secant was threatening to 2 do; correct?</p> <p>3 MR. GAGE: Objection.</p> <p>4 THE WITNESS: They didn't threaten 5 anything. They informed us.</p> <p>6 BY MR. FREESE:</p> <p>7 Q. You did not inform Health Canada that 8 Secant was alerting you that they were being 9 mandated not to sell you polypropylene mesh anymore; 10 correct?</p> <p>11 A. We did not.</p> <p>12 Q. And to your knowledge, no one else at 13 Ethicon, either in regulatory affairs or marketing 14 or compliance or global supply or legal, no one 15 suggested telling Health Canada about the Secant 16 issue; correct?</p> <p>17 MR. GAGE: Object to form.</p> <p>18 THE WITNESS: That's correct.</p> <p>19 BY MR. FREESE:</p> <p>20 Q. Do you know or have you seen what 21 Secant's response was to Mr. Sedlatschek's e-mail?</p> <p>22 A. I don't believe I did.</p> <p>23 Q. As you sit here today, Dr. Weisberg, 24 do you know if there even was a response to it?</p> <p>25 A. I don't know.</p>	<p>1 Q. -- the subject is Health Canada?</p> <p>2 A. Yes.</p> <p>3 Q. -- as per our discussion, could 4 medical please help to create a response to: In 5 addition, one or more revision surgeries may be 6 necessary to treat these complications, while some 7 complications may not always be completely 8 corrected.</p> <p>9 Do you see that?</p> <p>10 A. Yes.</p> <p>11 Q. And that was one of the questions 12 posed by Health Canada; correct?</p> <p>13 A. Yes.</p> <p>14 Q. And Ms. Kluesner was looking on how 15 to respond to that; correct?</p> <p>16 A. Yes.</p> <p>17 Q. And she came to you for that; 18 correct?</p> <p>19 A. Yes, she did.</p> <p>20 Q. And she said: Points we discussed 21 during our meeting -- and I assume that's a meeting 22 that you were in?</p> <p>23 A. Likely.</p> <p>24 Q. One of your Health Canada meetings?</p> <p>25 A. I suspect.</p>
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<p>1 Q. Is he still with the company?</p> <p>2 A. I believe he is.</p> <p>3 Q. Is he still in this same job?</p> <p>4 A. Yes.</p> <p>5 Q. Does he work here in Somerville?</p> <p>6 A. I don't know whether he's in 7 Somerville or in Cincinnati, or in New Brunswick for 8 that matter.</p> <p>9 MR. FREESE: All right, Dr. Weisberg. 10 I'm going to show you what I'm marking as Exhibit 11 1667.</p> <p>12 - - -</p> <p>13 (Deposition Exhibit No. P-1667, 4/14 14 E-Mail Chain, ETH.MESH.176324274 and 15 ETH.MESH.176324275, was marked for 16 identification.)</p> <p>17 - - -</p> <p>18 BY MR. FREESE:</p> <p>19 Q. I assume you've seen this document 20 before, sir?</p> <p>21 A. Yes.</p> <p>22 Q. Stacy Kluesner writes you in April of 23 2014 and says, quote, Hi, Marty -- that's you; 24 correct?</p> <p>25 A. Yes.</p>	<p>1 Q. -- it says, the need for the revision 2 surgery is independent of the mesh.</p> <p>3 A. Yes.</p> <p>4 Q. The mesh is fine, does not fail.</p> <p>5 A. Yes.</p> <p>6 Q. In these cases, the tissue's what 7 fails, do you see that?</p> <p>8 A. Yes.</p> <p>9 Q. Who came up with those points, those 10 bullet points?</p> <p>11 A. They were discussed at the meeting 12 and it was explained that when these operations 13 fail, it's not because the mesh rips or comes apart 14 or absorbs or goes away.</p> <p>15 It's because what it's attached to, 16 the tissue it's attached to, it may pull -- pull 17 loose or a part of the pelvic floor that's not 18 covered by the mesh may create a new recurrence.</p> <p>19 Q. Well, can we agree that whatever 20 surgery for revision is necessary is because of the 21 implantation of the mesh; correct? If the mesh 22 wasn't there, you wouldn't need a revision surgery, 23 would you?</p> <p>24 A. Well, it depends. If it's a -- if 25 it's a repeat pelvic floor prolapse -- the best</p>

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<p>1 example I can give you is that -- now, let's see 2 what device we're talking about. Anything -- okay. 3 If somebody does an anterior repair 4 of pelvic floor prolapse and somebody has another 5 prolapse, which is from the top of the vagina or the 6 bottom of the vagina, that's really due to the 7 tissue that's bad and you've fixed one part and the 8 other parts didn't get fixed, and that sometimes 9 happens, especially if you reinforce one part, 10 another part may pop through. 11 Q. In fact, that was an identified 12 complication of Prosima, was it not? 13 A. Yes. 14 Q. Because you repair one compartment 15 and you're causing a prolapse in another 16 compartment; correct? 17 A. Well, yeah, it goes for any kind of 18 pelvic floor repair, mesh or not. 19 MR. FREESE: Move to strike; 20 nonresponsive. 21 BY MR. FREESE: 22 Q. That was a known complication of a 23 Prosima, was it not? 24 A. Yes. 25 Q. Which used polypropylene mesh;</p>	<p>1 Q. So at least in that respect, that is 2 not a totally accurate statement, is it, that the 3 need for revision surgery is independent of the 4 mesh? 5 A. Well, I'm not sure that I made that 6 statement. This is what Stacy said that -- her 7 interpretation of what the results of the meeting 8 were. 9 Q. I understand. These are not your 10 words. So you do not agree that the literal things 11 she wrote there is correct, do you? 12 A. I agree in -- yeah, I do agree with 13 them. The mesh is generally fine and the mesh 14 itself doesn't fail, that's for sure. The need for 15 the revision surgery is independent of the mesh, I 16 think that the context of that at the meeting was 17 not what was discussed here; and in these cases, 18 could be in some cases, the tissue is what fails. 19 Q. In some cases. 20 A. Yeah. And in other cases, it wasn't 21 put in right. But usually a revision is -- when the 22 mesh comes out, it looks like when the mesh went in. 23 It's a little dirtier, but it's intact. It doesn't 24 have holes in it. 25 MR. FREESE: Move to strike as</p>
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<p>1 correct? 2 A. Yes. 3 Q. And the question that Ms. Kluesner is 4 asking is about complications. So the need for 5 revision surgeries independent of the mesh, that's 6 not a true statement, is it, because but for the 7 existence of the mesh, there wouldn't be a revision 8 surgery; correct, sir? 9 MR. GAGE: Object to form. 10 THE WITNESS: A revision surgery 11 might be necessary even if the mesh is functioning 12 as intended, but it might be a misplacement of the 13 mesh or it might be a tearing free of the mesh, but 14 the mesh when it's removed is -- appears the way it 15 does when it goes in. 16 MR. FREESE: Move to strike as 17 nonresponsive. 18 BY MR. FREESE: 19 Q. Dr. Weisberg, my question is simply 20 that you don't have revision surgery independent of 21 the mesh. The mesh is a necessary component of 22 needing a revision surgery, is it not? 23 A. It may be. 24 MR. GAGE: Objection. 25 BY MR. FREESE:</p>	<p>1 nonresponsive. 2 BY MR. FREESE: 3 Q. You asked her to send you IFUs. 4 A. Yes. 5 Q. To answer that question; correct? 6 A. Yes. 7 Q. And she says this is for all IFUs, 8 all TVTs, Gynemesh PS, and Artisyn Y's. Right? 9 A. Yes. 10 Q. And you write would you like all of 11 these, and you said unfortunately yes. 12 A. Yes. 13 Q. Because you wanted to look at all of 14 them. 15 A. Yes. 16 Q. And you did. 17 A. Yes. 18 (Pause.) 19 - - - 20 (Deposition Exhibit No. P-1668, 21 5/8/14 E-Mail Chain, ETH.MESH.17636165 22 through ETH.MESH.17636167, was marked for 23 identification.) 24 - - - 25 BY MR. FREESE:</p>

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<p>1 Q. Dr. Weisberg, I'm going to show you 2 what I've marked as P-1668. Have you seen that 3 document before, sir? 4 A. Let me read it, please. 5 Q. All right. 6 (Pause.) 7 THE WITNESS: Okay. Yes, I'm 8 familiar with this. 9 BY MR. FREESE: 10 Q. Did you review this in preparing your 11 -- for your deposition? 12 A. I reviewed a lot of documents. I 13 don't know if I reviewed this at that time, but I'm 14 familiar with the e-mail. 15 Q. Who is Dr. Caroline Charles? 16 A. She's a medical writer. 17 Q. Paid for by Ethicon? 18 A. Yes. 19 MR. GAGE: Object to form. 20 BY MR. FREESE: 21 Q. What does she write? 22 A. She is the one that takes our 23 information that we gather for our clinical 24 evaluation reports that we do on all of our products 25 on a regular basis and puts them into the format</p>	<p>1 with these retrospective/prospective studies is, 2 they are often conducted in single centers and the 3 authors do not always meticulously describe the 4 methods for data collection and analysis. I also 5 believe that the size of the cohorts would not allow 6 for a meta-analysis. We would need several 7 larger-scale studies. I tried to select the 8 information that was statistically significant, 9 however the information wasn't always clear in the 10 documents and sometimes there was no P values. 11 These only give us an indication that the number of 12 studies for TVT makes me think that the overall TVT 13 is no less safer than traditional surgery. But, 14 again, we would need robust, randomized, 15 multicenter, large-scale trials to confirm every 16 single point. 17 Do you see that? 18 A. I do. 19 Q. Is that a true statement? 20 A. I believe it is. 21 Q. Did you -- 22 A. For a limited number of studies that 23 she looked at. What I have to establish here is 24 whether she was doing -- whether the clinical 25 evaluation report she did had a limited number of</p>
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<p>1 that's required. 2 Q. Was she helping on the Health Canada 3 response? 4 A. I don't believe so. 5 Q. Why is she giving information to 6 Stacy Kluesner, re: Health Canada request? 7 A. Stacy may have reached out to -- and 8 this is a guess, but I think I recall that Stacy may 9 have reached out to her to get some information to 10 include in the Health Canada request. 11 Q. Do you see the question she poses: 12 Can you please assist in the rationale for why no 13 statistical methods were used to analyze the data, 14 different methodologies, endpoints, statistical 15 plans, et cetera? This can be generic. 16 Do you see that? 17 A. I'm trying to see where you're 18 reading. What -- 19 Q. The -- the first -- 20 A. Which date? 21 Q. The full paragraph here on the front 22 page here (Indicating). 23 A. Okay. Okay. Yes, I see that. 24 Q. And Dr. Charles writes to Stacy 25 Kluesner, she goes, I believe the -- the problem</p>	<p>1 years of studies that she -- that she looked at. I 2 don't know that. I don't remember. 3 Q. Can we agree that as of May 2014, 4 there were no robust, randomized, multicenter, 5 large-scale trials to confirm every single point 6 that is being discussed here? 7 A. No, that's not -- 8 MR. GAGE: Object to form. 9 THE WITNESS: That's not true. 10 BY MR. FREESE: 11 Q. That is what she says, is it not? 12 MR. GAGE: Object to form. 13 THE WITNESS: Well, that may be what 14 she says, but that's not true. What she says is 15 that you can't take these studies and put them 16 together to create a meta-analysis because the ways 17 that they were done weren't exactly -- or weren't 18 similar enough to be able to merge them into one new 19 study. That's what a meta-analysis is. 20 MR. FREESE: I understand that. And 21 you agree with that, that there was not enough 22 studies in existence as of 2014 to even do a proper 23 robust meta-analysis of the TVT studies; correct? 24 MR. GAGE: Object to form. 25 THE WITNESS: That's not what I said.</p>

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<p>1 BY MR. FREESE:</p> <p>2 Q. That is what Dr. Charles is saying,</p> <p>3 is it not?</p> <p>4 MR. GAGE: Object to form.</p> <p>5 THE WITNESS: Let me just read this</p> <p>6 again: Very wide variety of methods, patient</p> <p>7 selection, variable statistical analysis of POP-Q</p> <p>8 endpoint, et cetera. These</p> <p>9 retrospective/prospective studies is that they are</p> <p>10 often conducted in single centers.</p> <p>11 Okay. So she's talking about a lot</p> <p>12 of the publications that were not randomized,</p> <p>13 controlled. The size of the cohorts would not allow</p> <p>14 for a meta-analysis, need several larger-scale</p> <p>15 studies. I tried to select information that was</p> <p>16 statistically significant. Information wasn't</p> <p>17 always clear and there were no P values. This gives</p> <p>18 us an indication of the number of studies for TVT</p> <p>19 and makes us think that overall TVT is no less safe</p> <p>20 than traditional surgery, but again we would need</p> <p>21 robust, randomized, multicenter, large-scale trials</p> <p>22 to confirm every patient.</p> <p>23 BY MR. FREESE:</p> <p>24 Q. Do you agree with that?</p> <p>25 A. I really don't.</p>	<p>1 Q. The paid-for Ethicon consultant;</p> <p>2 correct?</p> <p>3 MR. GAGE: Object to form.</p> <p>4 BY MR. FREESE:</p> <p>5 Q. Right?</p> <p>6 A. He has consulted with Ethicon.</p> <p>7 Q. And so my question to you, sir, is</p> <p>8 since the time -- apparently Dr. Charles is just --</p> <p>9 she's unaware of all these studies you're talking</p> <p>10 about.</p> <p>11 MR. GAGE: Object to form.</p> <p>12 THE WITNESS: Well, she doesn't say</p> <p>13 whether she's aware of them or not.</p> <p>14 BY MR. FREESE:</p> <p>15 Q. Well, she says they don't exist and</p> <p>16 that she can conclude no more -- that TVT is no less</p> <p>17 safer than traditional surgery. Do you see that</p> <p>18 line?</p> <p>19 MR. GAGE: Object to form.</p> <p>20 THE WITNESS: I see that line.</p> <p>21 BY MR. FREESE:</p> <p>22 Q. And my question to you, sir, is, is</p> <p>23 that a different way of saying it's no more</p> <p>24 dangerous than traditional surgery?</p> <p>25 A. Well, you'd have to ask her what she</p>
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<p>1 Q. Did anybody tell Dr. Charles she was</p> <p>2 wrong?</p> <p>3 A. I did not. I don't specifically</p> <p>4 remember discussing this, although I suspect -- I'm</p> <p>5 remembering that we did discuss it and whether I</p> <p>6 gave an answer or not -- I know I didn't give it to</p> <p>7 her. Whether somebody else answered her or not, I</p> <p>8 don't know.</p> <p>9 Q. Well, sitting here today, you don't</p> <p>10 have your response in front of you; correct?</p> <p>11 A. No, I don't.</p> <p>12 Q. You don't remember what your response</p> <p>13 was; correct?</p> <p>14 A. It would have been the same as it was</p> <p>15 just now.</p> <p>16 Q. As we sit here today, did Ethicon</p> <p>17 ever do any more robust, randomized, multicenter,</p> <p>18 large-scale trials after 2014 to confirm any of the</p> <p>19 questions that Ms. Kluesner had at that time?</p> <p>20 A. We have over the -- the life of TVT</p> <p>21 probably a hundred randomized, controlled trials,</p> <p>22 including thousands of patients, and some of them go</p> <p>23 out as long as 17 years.</p> <p>24 Q. Yeah, Dr. Nilsson's study.</p> <p>25 A. Dr. Nilsson's study.</p>	<p>1 meant by that.</p> <p>2 Q. I'm asking you --</p> <p>3 A. No.</p> <p>4 Q. -- as a medical director, what does</p> <p>5 it mean to be no less safer than?</p> <p>6 A. Well, in the statistical world, there</p> <p>7 are equivalence studies which says things like no</p> <p>8 less safe or no less effective.</p> <p>9 And then there are other studies</p> <p>10 which are powered and controlled for, being able to</p> <p>11 say it's better, and there are many, many, many</p> <p>12 studies that show that.</p> <p>13 The -- of those hundred randomized,</p> <p>14 controlled studies, the safety and effectiveness has</p> <p>15 been consistent, not to the exact percentage, but</p> <p>16 within a highly successful range, and the safety has</p> <p>17 been also -- they have -- this is a device that has</p> <p>18 shown to be safe.</p> <p>19 MR. FREESE: Move to strike as</p> <p>20 nonresponsive.</p> <p>21 I didn't ask you anything at all</p> <p>22 about TVT, sir. I simply asked you to define what</p> <p>23 no less safer means. That's all I asked you.</p> <p>24 Do you understand that was my</p> <p>25 question?</p>

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<p>1 THE WITNESS: That's in the beginning 2 of my question -- the beginning of my answer. 3 BY MR. FREESE: 4 Q. Well, I move to -- all I asked you 5 was, what does no less safer mean. 6 A. It's a statistical term. 7 MR. FREESE: I move to strike 8 everything after it's -- everything other than "It's 9 a statistical term." 10 (Pause.) 11 MR. FREESE: Dr. Weisberg, I want to 12 show you what I've marked as P-1669. 13 - - - 14 (Deposition Exhibit No. P-1669, 15 6/2/14 PRE14-055S Health Canada Section 39 16 Request and Response, ETH.MESH.17639467, 17 was marked for identification.) 18 - - - 19 BY MR. FREESE: 20 Q. And this is a -- it looks like a 21 Power Point presentation on the Health Canada 22 Section 39 request and response. Do you see that? 23 A. Yes. 24 Q. Dated June 2nd, 2014? 25 A. Yes.</p>	<p>1 looking at page 5, what was requested in part was 2 the labeling that contains up-to-date information on 3 potential complications as listed by Health Canada. 4 A. Yes. 5 Q. And if you'll look on page 9, it says 6 results of investigation. Do you see that? 7 A. Yes. 8 Q. And it says: Changes are required in 9 the global labeling due to Health Canada's Section 10 39 request and to align with FDA's proposed rule. 11 Do you see that? 12 A. Yes. 13 Q. And I think you mentioned this 14 earlier, but this started off as just changing the 15 IFUs for Health Canada. At some point, the company 16 decided to change its IFUs worldwide. 17 A. Yes. 18 Q. For all of the TVTs, the Gynemesh, 19 and Artisyn Y? 20 A. Yes. 21 Q. And was this document created in the 22 normal course of business by Ethicon? 23 A. Yes. 24 Q. By Ethicon employees? 25 A. Yes.</p>
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<p>1 Q. Are you familiar with this document? 2 A. I am. 3 Q. Did you help author any part of it? 4 A. I didn't put it together, but it was 5 put together with the team that I worked with. 6 Q. All right. Can you describe for me 7 what this document is, please, sir? 8 A. Let me just look through it to make 9 sure that... 10 (Pause.) 11 THE WITNESS: This is a -- I believe 12 this is a quality board document. 13 BY MR. FREESE: 14 Q. For Health Canada? 15 A. Yes. I'm not a hundred percent sure. 16 This is obviously a presentation made to people not 17 directly involved on the Health Canada team, so this 18 is a presentation that was made, it looks like a 19 presentation that was for -- it was for quality 20 board review, yeah. I'm sorry. 21 Q. And it describes what went on, that 22 is, the request coming into Johnson & Johnson from 23 Health Canada March 24th, 2014? 24 A. Yes. 25 Q. And it says requested, and I'm</p>	<p>1 Q. At or about the time that it was 2 prepared on June 2nd, 2014? 3 A. Yes. 4 Q. And does the information here to the 5 best of your knowledge appear to be correct and 6 accurate? 7 A. Yes. 8 Q. And if you'll look on page -- 9 starting on page 12. It says labeling changes to be 10 made. Do you see that? 11 A. Yes. 12 Q. And it lists across there the changes 13 made to the labeling for TVT, Gynemesh PS, and 14 Artisyn. Do you see that? 15 A. Yes. 16 Q. And if you'll -- they have an adverse 17 events section. Do you see that? 18 A. I do. 19 Q. Then there's a labeling modification, 20 do you see that, for the adverse events? 21 A. Yes. 22 Q. And then there's a section, labeling 23 additions, adverse events section. Do you see that? 24 A. Yes. 25 Q. And that means that -- that the</p>

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<p>1 things listed on here were additions to the IFU that</p> <p>2 did not previously exist; correct?</p> <p>3 MS. KABBASH: Rich, are you talking</p> <p>4 about page 15 of the slide deck?</p> <p>5 MR. FREESE: Yes.</p> <p>6 THE WITNESS: 15?</p> <p>7 MR. FREESE: Yes, sir.</p> <p>8 THE WITNESS: I'm sorry.</p> <p>9 MR. FREESE: I'm walking you through</p> <p>10 each page.</p> <p>11 THE WITNESS: Okay.</p> <p>12 MR. FREESE: Page 12 lists the</p> <p>13 adverse events, under new section other adverse</p> <p>14 events.</p> <p>15 THE WITNESS: Yes.</p> <p>16 MR. FREESE: Page 13 is labeling</p> <p>17 modification adverse events, same for page 14. And</p> <p>18 page 15 is labeling additions adverse events</p> <p>19 section.</p> <p>20 Do you see that?</p> <p>21 THE WITNESS: Right.</p> <p>22 MR. FREESE: Okay.</p> <p>23 THE WITNESS: Page 14 is labeling</p> <p>24 modifications. Page 15 is labeling additions.</p> <p>25 BY MR. FREESE:</p>	<p>1 there, orange is attributing the adverse event to</p> <p>2 litigation; correct?</p> <p>3 A. Yes.</p> <p>4 Q. Blue is attributed to nonlitigation;</p> <p>5 correct?</p> <p>6 A. Correct.</p> <p>7 Q. And the green line is the rate?</p> <p>8 A. Yes.</p> <p>9 Q. Okay.</p> <p>10 My question, sir, is, how does</p> <p>11 Ethicon track whether or not a complaint is</p> <p>12 litigation related or not?</p> <p>13 A. Well, they can't be a hundred percent</p> <p>14 accurate, but the complaints that have come from</p> <p>15 doctors or patients themselves are what you see at</p> <p>16 the top of each column in blue.</p> <p>17 Everything in orange comes from</p> <p>18 attorneys.</p> <p>19 Q. So if a lawsuit was filed -- is this</p> <p>20 like a lawyer files an adverse event or is Ethicon</p> <p>21 simply counting the number of lawsuits filed against</p> <p>22 it in order to come up with that number?</p> <p>23 A. Any time we learn of an adverse</p> <p>24 event, whether it's walking down the street and</p> <p>25 talking to somebody, reading an article in the</p>
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<p>1 Q. And it lists here all the additions</p> <p>2 to the IFU in the adverse events section; correct?</p> <p>3 A. Correct.</p> <p>4 Q. It lists that there -- all these</p> <p>5 things are going to be put into TVT's IFUs; correct?</p> <p>6 A. That's correct.</p> <p>7 Q. And one of the -- strike that.</p> <p>8 And then if you'll look over at page</p> <p>9 18, Dr. Weisberg, there's a -- there's some --</p> <p>10 several graphs. Do you see that?</p> <p>11 A. I do.</p> <p>12 Q. And are these charts intended to</p> <p>13 document adverse event reports?</p> <p>14 A. Yes.</p> <p>15 Q. And there's a spike in adverse event</p> <p>16 reports between, I guess, March-April of 2013</p> <p>17 through December of 2013; is that correct?</p> <p>18 A. That's correct.</p> <p>19 Q. What was the purpose of these charts</p> <p>20 being prepared?</p> <p>21 A. We do this every week with all of our</p> <p>22 complaints during our adverse event meeting. We do</p> <p>23 it weekly and we do it monthly so we can track</p> <p>24 adverse events.</p> <p>25 Q. And if you'll look on the legend</p>	<p>1 paper, casually being at dinner with somebody who</p> <p>2 said, you know, I had your device and it didn't</p> <p>3 work, even to the point of I don't like the color of</p> <p>4 the box, all of that goes in as a complaint. And</p> <p>5 it's the role of every Ethicon employee to report</p> <p>6 any adverse event that they learn about.</p> <p>7 Q. I understand, but my question is, I</p> <p>8 mean, you're tracking literally numbers of</p> <p>9 complaints and ascribing them to litigation in here.</p> <p>10 A. Well, the information is given to us</p> <p>11 by our legal department that these many -- that the</p> <p>12 -- they received notices on these cases and they're</p> <p>13 counted as complaints.</p> <p>14 Q. That's my point. So if a -- if a</p> <p>15 woman has a complication from a TVT mesh, has</p> <p>16 surgery, multiple surgeries, and doesn't file a</p> <p>17 lawsuit, that doesn't show up in this list unless</p> <p>18 she or her doctor reports it; correct?</p> <p>19 A. That's correct.</p> <p>20 Q. If however -- but if a lawsuit's</p> <p>21 filed on behalf of that woman where she's got a</p> <p>22 complication, it gets counted; correct?</p> <p>23 A. That's correct.</p> <p>24 Q. So had the lawsuit not been filed and</p> <p>25 the doctor didn't report it or the patient didn't</p>

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<p>1 report it, it never would have gotten counted, would 2 it?</p> <p>3 A. That's correct.</p> <p>4 Q. So the lawsuits do help you track 5 more accurately the number of adverse events, do 6 they not?</p> <p>7 MR. GAGE: Object to form.</p> <p>8 THE WITNESS: Well, it gives us the 9 opportunity to look into all these cases.</p> <p>10 BY MR. FREESE:</p> <p>11 Q. Because otherwise you might have an 12 adverse event that didn't otherwise get reported; 13 correct?</p> <p>14 A. That's correct.</p> <p>15 MR. GAGE: Object to form.</p> <p>16 BY MR. FREESE:</p> <p>17 Q. You would agree with me that the 18 number of adverse events are normally well 19 underreported, are they not?</p> <p>20 A. I believe that's true.</p> <p>21 Q. In other words, the number of 22 complications from TVT, generally, the ones that are 23 actually reported are much less than the actual 24 complications that are existing in society as a 25 whole.</p>	<p>1 to see what we can learn from it and to see whether 2 there's something we can do to make sure that we 3 minimize the bad things that happen when people have 4 operations.</p> <p>5 Q. Well, what has Ethicon done to 6 minimize the bad things that happen from 7 complications because of these litigation charts 8 that you got here?</p> <p>9 A. Well, you know, you're asking a very 10 broad question.</p> <p>11 Q. Yes, sir.</p> <p>12 A. The things that have happened -- I 13 can give you some general -- I'll have to give you a 14 broad answer.</p> <p>15 Q. Well, let me withdraw the question 16 then.</p> <p>17 A. Okay.</p> <p>18 Q. Do you agree with me, Dr. Weisberg, 19 that to the extent that the lawsuits have alerted 20 Ethicon to complications arising out of the use of 21 its products that it didn't otherwise know of is a 22 good thing?</p> <p>23 MR. GAGE: Object to form.</p> <p>24 THE WITNESS: I don't know that we 25 got any new complications or adverse events, but</p>
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<p>1 A. I think that's generally true.</p> <p>2 Q. All right.</p> <p>3 And you're not ascribing any question 4 as to the merits or lack of merits if it's 5 litigation -- strike that.</p> <p>6 In the columns that are listing the 7 number of complaints versus -- litigation versus 8 nonlitigation, this is not an attempt to quantify by 9 merits whether or not it's a valid complaint; 10 correct?</p> <p>11 A. Not at all.</p> <p>12 Q. What is the purpose of tracking it by 13 litigation as opposed to nonlitigation?</p> <p>14 A. Well, I can't really answer why they 15 do that, except to explain why there's a spike, and 16 that spike may mean that more of these cases are 17 being reported that weren't being reported at all. 18 And it's still a spike. You know, we still need to 19 look into it.</p> <p>20 Sometimes the --</p> <p>21 Q. Go ahead.</p> <p>22 A. Sometimes the litigation reports are 23 harder to get information from to try to investigate 24 the complaints, but every one of them -- there's an 25 attempt to investigate every complaint that comes in</p>	<p>1 certainly we're able to see the -- how widespread, 2 at least complaints of such events are, and, yes, it 3 helps us.</p> <p>4 BY MR. FREESE:</p> <p>5 Q. Because that -- these lawsuits that 6 are being reported here may very well alert you to 7 complications you wouldn't otherwise have seen in 8 any reporting database; correct?</p> <p>9 MR. GAGE: Object to form.</p> <p>10 THE WITNESS: That's correct. Any 11 time we learn about a complication and can 12 investigate it and see what the story is, it makes 13 us better.</p> <p>14 BY MR. FREESE:</p> <p>15 Q. And who at Ethicon's in charge of 16 investigating all of these lawsuits to see whether 17 or not they are valid adverse events?</p> <p>18 MR. GAGE: Object to form.</p> <p>19 THE WITNESS: Our quality department 20 tries to investigate every case. Sometimes with the 21 litigation cases, we don't get answers.</p> <p>22 BY MR. FREESE:</p> <p>23 Q. When -- strike that.</p> <p>24 You understand that many, many, many 25 of the women who have filed lawsuits against J & J</p>

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<p>1 over their TVT products or their -- or their 2 prolapse products have had to have revision 3 surgeries; correct? You do know that. 4 MR. GAGE: Object to form. 5 THE WITNESS: I know that some have. 6 I don't know how you're defining many, many, many. 7 MR. FREESE: A -- a -- not a hundred 8 percent, but a double digit percent of the women who 9 filed complaints have had to have additional 10 surgeries arising from complications out of the use 11 of a POP or SUI product. 12 MR. GAGE: Object to form. 13 BY MR. FREESE: 14 Q. You know that. 15 A. I can't answer that specifically. I 16 would have to look at it case by case. There are 17 lots of reasons that people need additional surgery. 18 Q. Well, let me ask you this, sir: Is 19 it your belief that any of the surgeries that are 20 being done by doctors in this country for 21 complications arising out of the use of an SUI or 22 POP product are unnecessary surgeries? 23 MR. GAGE: Object to form; beyond the 24 scope. 25 THE WITNESS: I can't answer that.</p>	<p>1 BY MR. FREESE: 2 Q. Who in quality tracks whether or not 3 surgeries are necessary in the view of Ethicon? 4 MR. GAGE: Beyond the scope. 5 Objection; beyond the scope. 6 THE WITNESS: Each individual case is 7 evaluated, and I don't know that we keep a record of 8 how many need un -- had a what we consider 9 unnecessary surgery or may not have needed surgery. 10 I mean, you know, we're very limited. 11 We don't know the patient. We haven't seen the 12 patient. We haven't seen the X-rays, et cetera, but 13 we do track that and if you look at any individual 14 case, if we were able to gather enough information, 15 we may make a comment that there were other ways 16 that may have been taken care of this complaint. 17 BY MR. FREESE: 18 Q. All right. But my question to you 19 is, who is in charge of that department -- that 20 quality assurance department in Ethicon that tracks 21 whether or not surgeries are necessary? 22 MR. GAGE: Objection; scope. 23 THE WITNESS: That's a compound 24 question. Who's in charge of -- 25 MR. FREESE: Of -- you said the</p>
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<p>1 BY MR. FREESE: 2 Q. As you sit here today, you have no 3 evidence that any surgery being performed on a woman 4 to repair a complication from an injury related to 5 mesh was an unnecessary surgery. 6 MR. GAGE: Object to form; beyond the 7 scope. 8 THE WITNESS: I can't answer that. 9 BY MR. FREESE: 10 Q. Has anybody at Ethicon ever looked at 11 that question, whether or not women are having 12 unnecessary surgeries? 13 MR. GAGE: Object to form; beyond the 14 scope. 15 THE WITNESS: We try to look at every 16 complaint individually and there are some that 17 appear to have surgery that could have been avoided. 18 MR. FREESE: Okay. 19 THE WITNESS: And others where it 20 appears that it was a necessary surgery. 21 BY MR. FREESE: 22 Q. Who tracks that? 23 MR. GAGE: Object to form -- 24 THE WITNESS: Quality. 25 MR. GAGE: -- beyond the scope.</p>	<p>1 person who tracks whether or not surgeries that 2 women are having to correct complications from mesh 3 is done in the quality department. I'm asking you 4 who's in charge of that. 5 A. I don't know -- 6 MR. GAGE: Objection; scope. 7 THE WITNESS: I'm sorry. I don't 8 know that it's tracked. It's investigated, but I 9 don't know that it's tracked. 10 MR. FREESE: I may have misunderstood 11 your testimony. 12 (Pause.) 13 BY MR. FREESE: 14 Q. Did Health Canada ask any questions 15 about degradation of the mesh? 16 A. No. 17 Q. And did you supply them any 18 information about evidence of degradation of the 19 mesh? 20 A. The mesh is clinically nondegradable, 21 and that's in the IFU. 22 MR. FREESE: Move to strike, 23 nonresponsive. 24 BY MR. FREESE: 25 Q. I simply asked you, did you supply</p>

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<p>1 any information to Health Canada regarding 2 degradation of the mesh? 3 A. Yes. 4 Q. And was it supplied because it was 5 already in the IFU? 6 A. Yes. 7 Q. So -- we can look at that. Is that 8 the phrase, under the action section, of animal 9 studies show that implantation of Prolene mesh 10 elicits a minimal inflammatory reaction in tissues 11 which is transient followed by the deposition of 12 thin fibrous tissue layers that can grow through the 13 interstices of the mesh, thus incorporating the mesh 14 into adjacent tissue. The material is not absorbed, 15 nor is it subject to degradation or weakening or 16 action of tissue enzymes, is that the phrase you 17 were referring to? 18 A. That's correct. 19 Q. And that didn't change. 20 A. That didn't change. 21 Q. And they didn't ask you about that. 22 A. No, they didn't. 23 Q. Did you share with them any of your 24 studies showing that mesh did degrade? 25 MR. GAGE: Object to form.</p>	<p>1 MR. FREESE: -- TVTs were causing 2 complication in women. Are you familiar with that 3 report? 4 MR. GAGE: Object to form. 5 THE WITNESS: Yes, I am. 6 BY MR. FREESE: 7 Q. Was the PA Consulting study shared 8 with Health Canada? 9 A. No. 10 MR. FREESE: I'm trying to zip 11 through my questions here to get us going. 12 Let's go ahead -- I think he needs to 13 change the tape anyway. Let's take five minutes. 14 Let me look at my notes. 15 THE VIDEO TECHNICIAN: The time is 16 1:06. We are going off the record. 17 - - - 18 (A discussion off the record 19 occurred.) 20 - - - 21 (A luncheon recess was taken from 22 1:07 p.m. until 1:56 p.m.) 23 - - - 24 (Whereupon, the following discussion 25 took place off the videotape record:</p>
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<p>1 THE WITNESS: We discussed a study 2 that was done a long time ago and concluded that any 3 degradation, as minimal as it is, did not affect the 4 strength or the weight of -- it was a suture study 5 and it was in dogs. It did not affect either the 6 strength or the weight of the polypropylene. 7 So, clinically, it doesn't -- it 8 doesn't degrade in any way to -- it's not clinically 9 significant. It's not clinically important. 10 MR. FREESE: Move to strike as 11 nonresponsive. 12 BY MR. FREESE: 13 Q. Dr. Weisberg, did you share the PA 14 Consulting study with Health Canada? 15 A. The PA Consulting -- 16 MR. GAGE: Object to form. 17 BY MR. FREESE: 18 Q. First of all, are you familiar with 19 the PA Consulting study? 20 MR. GAGE: Object to form. 21 THE WITNESS: I would need to see it. 22 MR. FREESE: It's a London-based 23 company that Ethicon hired to review all the science 24 and literature on why -- 25 THE WITNESS: Oh --</p>	<p>1 - - - 2 MR. GAGE: So, Madam Court Reporter, 3 I have on my speakerphone, my being William Gage, 4 Rich Bernardo, who is counsel for Ethicon and 5 Johnson & Johnson, in this litigation along with 6 Alex Barlow and Rich Freese. 7 And Mr. Freese has asked us to make 8 certain stipulations with regard to some of the 9 documents that were shown to Dr. Weisberg over the 10 past two days, and I believe we have an 11 understanding or an agreement that we need to 12 memorialize on the record. 13 MR. BERNARDO: This is Rich Bernardo, 14 who, for the record, is not at the deposition, but 15 is calling in telephonically. 16 Mr. Freese and myself and some 17 colleagues representing Ethicon have been engaged in 18 ongoing discussions with respect to evidentiary 19 issues and documentary issues; and we've come to an 20 agreement for purposes of certain cases, including 21 the Texas cases in this litigation, not to object on 22 the grounds of business record to e-mails composed 23 or created by Ethicon employees. 24 But we do point out, as we have in 25 our prior discussions with Mr. Freese, that we do</p>

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<p>1 not agree as a legal matter that every e-mail the 2 company creates does constitute a business record. 3 Rather, we're doing this as an accommodation to get 4 by a number of issues and we certainly do reserve 5 our right in certain circumstances to raise that 6 issue. 7 And we will also agree as to those 8 documents or e-mails that are not created by 9 Ethicon, but indicate from their face that they were 10 received by an Ethicon employee, that they were, in 11 fact, received by that Ethicon employee in 12 connection with his business and received by any 13 individual from whose custodial file the record was 14 collected. 15 Rich, does that accurately reflect 16 what you and I have been discussing? 17 MR. FREESE: Yeah, with a couple of 18 additions: That the recipient of the e-mail or the 19 holder of the e-mail in their custodial file was on 20 notice of the information contained therein. 21 And the only other thing I would say 22 is, you said you -- I understand you're not making a 23 blanket agreement that all e-mails forever are 24 business records of Johnson & Johnson and you are 25 reserving that right.</p>	<p>1 things that we pointed out we would not agree to as 2 falling within business records, even though they 3 are e-mails, are e-mails of a personal nature or 4 e-mails of such language that clearly are not 5 business related and other examples like that. 6 We've had those discussions a number 7 of times. I think we've come to agreement on that, 8 and that's one of the reasons that I'm reserving for 9 Ethicon its right to object to certain documents and 10 not making a blanket statement here. 11 MR. FREESE: Yeah, and that's fine, 12 Rich, and I don't think we have any of those in 13 front of us today, so -- 14 MR. BERNARDO: Perfect. 15 MR. GAGE: Are you all done? 16 MR. BARLOW: Yeah. 17 MR. GAGE: Thank you, Rich. We very 18 much appreciate it. 19 MR. BERNARDO: My pleasure.) 20 - - - 21 (A discussion off the record 22 occurred.) 23 - - - 24 THE VIDEO TECHNICIAN: The time is 25 2:01. We're back on the record.</p>
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<p>1 In cases other than the ones that 2 you're agreeing -- you're not going to reserve it in 3 this one because we haven't accomplished anything 4 then. You're reserving it generally, but you're not 5 going to assert it in this litigation on the 6 particular documents that we're making the agreement 7 on. 8 MR. BERNARDO: That is correct. 9 MR. BARLOW: And by this litigation, 10 you mean the MDL litigation, the New Jersey 11 litigation, or Mr. Freese's cases. Right? 12 MR. BERNARDO: That is correct. 13 MR. GAGE: And so now I think the 14 only task that remains at hand is, we do have to go 15 through and pull out of the stack of the exhibits 16 those documents which do not fall within the scope 17 of this agreement, things such as the list of 18 witnesses that he -- I mean, the list of people on 19 the various teams that he created and a couple of 20 other documents. 21 MR. BARLOW: Documents that weren't 22 created by Ethicon -- 23 MR. BERNARDO: One additional point 24 that Mr. Gage reminds me of is, Mr. Freese, in 25 connection with our discussions, one example of</p>	<p>1 - - - 2 EXAMINATION 3 - - - 4 BY MR. GAGE: 5 Q. Good afternoon, Dr. Weisberg. My 6 name is William Gage. I'm an attorney for Ethicon 7 and Johnson & Johnson, and I have some questions to 8 ask you. 9 A. Okay. 10 Q. The first document that you have 11 there in front of you is marked P-1608; correct? 12 A. Yes. 13 Q. And you were asked some questions, I 14 think yesterday, about that document; correct? 15 A. Yes. 16 Q. Would you tell the jury what this 17 document is? 18 A. The document's a request from Health 19 Canada for additional information on some of our 20 medical devices. 21 Q. And you've been testifying for a day 22 and a half about generally the Health Canada 23 request; correct? 24 A. Correct. 25 Q. And this is the document that</p>

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<p>1 constitutes the Health Canada request that was sent 2 to Ethicon and about which we have generally been 3 discussing for the past day and a half; correct? 4 A. Yes. 5 MR. GAGE: All right. Dr. Weisberg, 6 I'm handing you -- what number is the exhibit number 7 on that? What is the next exhibit number, ma'am; do 8 you know? 9 MR. FREESE: It's going to be on 10 whatever those stickers are. 11 (Pause.) 12 MR. GAGE: Does it still say P? It 13 doesn't say P-1670. 14 MR. FREESE: I think they have been 15 saying that. I was kind of thrown off by that. 16 MR. GAGE: It says P, even if it's 17 one of my exhibits, a defense exhibit? 18 THE COURT REPORTER: (Indicating.) 19 THE VIDEO TECHNICIAN: Off the 20 record? 21 MR. FREESE: Off the record. Sure. 22 THE VIDEO TECHNICIAN: The time is 23 2:03. We're going off the record. 24 - - - 25 (A discussion off the record)</p>	<p>1 Q. Is it a response with attachments? 2 A. It's a response letter with a number 3 of attachments. 4 Q. Was that document and the 5 attachments, were they made at or near the time of 6 the events described in the documents by person or 7 persons with actual knowledge? 8 A. Yes. 9 Q. And was the writing and those 10 attachments made in the regular course of Ethicon's 11 business? 12 A. Yes. 13 Q. And was it Ethicon's regular business 14 practice to make that record or document? 15 A. Yes. 16 Q. And Dr. Weisberg, as I understand it, 17 you were the medical director -- the Ethicon medical 18 director who was the most heavily involved in the 19 Health Canada response; is that correct? 20 A. That's correct. 21 Q. Tell the jury, if you would, a little 22 bit about your background and training, just 23 briefly. 24 A. I am a gynecologist. I practiced for 25 -- from -- I was at Thomas Jefferson University</p>
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<p>1 occurred.) 2 - - - 3 THE VIDEO TECHNICIAN: The time is 4 2:04. We're back on the record. 5 - - - 6 (Deposition Exhibit No. D-1, Ethicon 7 Response to Section 39 Request and 8 Attachments, ETH.MESH.22631022 through 9 ETH.MESH.22632029, was marked for 10 identification.) 11 - - - 12 BY MR. GAGE: 13 Q. Dr. Weisberg, I'm handing you a 14 document that is marked D-1. Are you familiar with 15 that document? 16 A. Yes. 17 Q. And what is that document? 18 A. This is the response to the Health 19 Canada request. 20 Q. And when you say the response, you're 21 talking about Ethicon's response? 22 A. Ethicon's response to their request. 23 Q. And what is that comprised of? 24 What's the -- just generally? 25 A. The --</p>	<p>1 Hospital from 1972 through the year 2000, practicing 2 gynecology. After that, I came to work at Ethicon 3 as a medical director. 4 Q. So what did you do between -- what do 5 you do now? 6 A. I retired on August the 31st and 7 started back as a contractor part-time for Ethicon 8 on September 1st, and that's what I'm doing now. 9 Q. So were you a medical director at 10 Ethicon from 2000 through the mid part of 2015? 11 A. Yes. 12 Q. And what, if any, gynecological 13 meshes were you responsible for during that 14 timeframe? 15 A. Throughout that period, I -- I 16 participated in -- in almost all of the 17 gynecological meshes at one time or another. 18 Q. Would that have included the TVT 19 family of products? 20 A. Yes. 21 Q. Would that have included Gynemesh PS? 22 A. Yes. 23 Q. And at the time that you retired in 24 August of 2015, the Health Canada response and the 25 IFU changes that resulted from that process had</p>

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<p>1 already been implemented; correct?</p> <p>2 A. Yes.</p> <p>3 Q. Now, sir, when -- did you work as</p> <p>4 part of a team in preparing the response to the</p> <p>5 Health Canada inquiry?</p> <p>6 A. Yes, I did.</p> <p>7 Q. When your team began the process of</p> <p>8 making changes to the various IFUs we've discussed,</p> <p>9 was any consideration given by your team of the</p> <p>10 number of years that these various devices had been</p> <p>11 on the market?</p> <p>12 A. Yes.</p> <p>13 Q. Why?</p> <p>14 A. Because it's data. It's confirmed,</p> <p>15 published evidence, and that's really the best way</p> <p>16 to know how a product is behaving and interacting</p> <p>17 and is being used and how successful it is.</p> <p>18 Q. And when you talk about published</p> <p>19 data, what are you speaking of in particular?</p> <p>20 A. Generally, randomized, controlled</p> <p>21 studies that are published in medical journals.</p> <p>22 Q. What are randomized, controlled</p> <p>23 studies?</p> <p>24 A. Randomized -- we'll break that down.</p> <p>25 A randomized study is one in which one group</p>	<p>1 that.</p> <p>2 The team that was responsible for</p> <p>3 preparing the response to the Health Canada inquiry</p> <p>4 obviously did its work in 2015, because the inquiry</p> <p>5 from Health Canada first arrived in 2015; is that</p> <p>6 correct?</p> <p>7 A. Correct.</p> <p>8 MR. FREESE: Object to the form of</p> <p>9 the question. Do you mean '14?</p> <p>10 THE WITNESS: Oh --</p> <p>11 MR. FREESE: The request, was it --</p> <p>12 THE WITNESS: I'm sorry. The request</p> <p>13 was in March of '14.</p> <p>14 MR. GAGE: I'm sorry. Strike that.</p> <p>15 Let me ask the question.</p> <p>16 THE WITNESS: Thank you.</p> <p>17 BY MR. GAGE:</p> <p>18 Q. The work that your team did was to</p> <p>19 perform -- strike it. Let me start it over.</p> <p>20 The work that your team did began in</p> <p>21 2014 after receiving the Health Canada inquiry in</p> <p>22 2014; is that correct?</p> <p>23 A. That's correct.</p> <p>24 Q. As of the time that your team</p> <p>25 prepared the response, how many years of data was</p>
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<p>1 receives an investigational device -- now,</p> <p>2 investigational doesn't necessarily mean that it</p> <p>3 hasn't been approved, but the device that you're</p> <p>4 investigating in this study -- and another group has</p> <p>5 the same procedures done with other devices or other</p> <p>6 methods and you get to -- patients are randomly</p> <p>7 assigned into these groups to avoid bias.</p> <p>8 And you compare the results of the --</p> <p>9 of the two groups to see if one is better, worse, as</p> <p>10 good as the other.</p> <p>11 Q. What is the significance, if any, of</p> <p>12 that process as viewed by the medical and scientific</p> <p>13 community?</p> <p>14 A. Randomized, controlled studies are --</p> <p>15 MR. FREESE: Object to the form of</p> <p>16 the question.</p> <p>17 You can go ahead.</p> <p>18 THE WITNESS: Randomized, controlled</p> <p>19 studies are considered the best kinds of studies</p> <p>20 because the same things are looked for in each</p> <p>21 group, the same -- as many parameters as can be are</p> <p>22 the same in each group, and the only variant is the</p> <p>23 device that you're testing.</p> <p>24 BY MR. GAGE:</p> <p>25 Q. The team that responded -- or strike</p>	<p>1 already in existence with regard to the TVT line of</p> <p>2 products?</p> <p>3 A. Well, we had studies that looked at</p> <p>4 women who had it in for 17 years, but the device was</p> <p>5 launched in 1997 and there were papers back that</p> <p>6 far.</p> <p>7 Q. And which device specifically are you</p> <p>8 referring to?</p> <p>9 A. That would be the TVT Retropubic.</p> <p>10 Q. When was the TVT-O launched?</p> <p>11 A. In 2004.</p> <p>12 Q. How many years of data did your team</p> <p>13 have available, as of the time it began working on</p> <p>14 the response to the Health Canada inquiry, with</p> <p>15 regard to TVT-O?</p> <p>16 A. Ten.</p> <p>17 Q. Do you know how many randomized</p> <p>18 clinical trials had been performed on the TVT device</p> <p>19 as of 2014 when your team was working on the</p> <p>20 response to the Health Canada inquiry?</p> <p>21 MR. FREESE: Object to the form of</p> <p>22 the question.</p> <p>23 THE WITNESS: On the retropubic, a</p> <p>24 little over a hundred. The obturator, a little over</p> <p>25 60.</p>

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<p style="text-align: right;">Page 466</p> <p>1 BY MR. GAGE:</p> <p>2 Q. Who performed those studies?</p> <p>3 A. They were performed by a number of</p> <p>4 people independently. There were some studies that</p> <p>5 were funded by Ethicon, but most were not.</p> <p>6 Q. How many women were involved</p> <p>7 collectively in these studies?</p> <p>8 A. Thousands. I don't have an exact</p> <p>9 number.</p> <p>10 Q. Now, you talk about the studies being</p> <p>11 published. Where were these studies that contain</p> <p>12 this data published?</p> <p>13 A. In medical journals.</p> <p>14 Q. And just help us understand what</p> <p>15 medical journals are.</p> <p>16 A. Medical journals are magazines,</p> <p>17 publications, to which people submit articles that</p> <p>18 are then vetted by an editorial board who reviews</p> <p>19 the articles for the content, the statistics, the</p> <p>20 investigative technique; and then it's decided by</p> <p>21 that medical board -- by that editorial board</p> <p>22 whether an article is worthy of publication.</p> <p>23 Q. Putting aside randomized clinical</p> <p>24 trials, were there other kinds of studies that had</p> <p>25 been performed on TVT and TVT-O at the time your</p>	<p style="text-align: right;">Page 468</p> <p>1 BY MR. GAGE:</p> <p>2 Q. Did your team reach any conclusions</p> <p>3 with regard to the safety of the TVT?</p> <p>4 A. Yes.</p> <p>5 Q. What were those conclusions?</p> <p>6 A. That this was a relatively safe</p> <p>7 device.</p> <p>8 Q. Did the team reach any conclusions</p> <p>9 with regard to the efficacy of the TVT device?</p> <p>10 A. Yes.</p> <p>11 Q. And what were those conclusions?</p> <p>12 A. That almost all the publications said</p> <p>13 that it was a very effective device.</p> <p>14 Q. Did the team reach any conclusions</p> <p>15 with regard to the safety of the TVT-O device?</p> <p>16 A. They concluded that that, too, was a</p> <p>17 safe device, relatively safe device.</p> <p>18 Q. And did the team reach any</p> <p>19 conclusions with regard to the efficacy or</p> <p>20 effectiveness of the TVT-O device?</p> <p>21 A. They did and that was -- oh. They</p> <p>22 did.</p> <p>23 Q. And what was that conclusion?</p> <p>24 A. That the TVT-O is also an effective</p> <p>25 device.</p>
<p style="text-align: right;">Page 467</p> <p>1 team began work on the response to Health Canada?</p> <p>2 A. Many others.</p> <p>3 Q. What kinds of studies are those</p> <p>4 briefly?</p> <p>5 A. Well, and -- it's probably in the</p> <p>6 range of a thousand -- there are case reports.</p> <p>7 There are case series, and what that is is a doctor</p> <p>8 says, gee, I've done this many of these procedures,</p> <p>9 I want to tell people how I do it and what my</p> <p>10 results are. Or it may be a list of these are the</p> <p>11 procedures I've done and these are some</p> <p>12 complications that I've -- that I've come up</p> <p>13 against. Or it just may be -- just a history of how</p> <p>14 somebody treats urinary stress incontinence.</p> <p>15 Q. As your team was working on changes</p> <p>16 to the IFU, did the team reach any conclusion with</p> <p>17 regard to the safety -- the safety profile of the</p> <p>18 TVT device based on those studies?</p> <p>19 A. Yeah, looking at all the articles and</p> <p>20 everything that we researched and knew about,</p> <p>21 because we'd really been following these things all</p> <p>22 along, it was clear that this is an effective and a</p> <p>23 very safe device.</p> <p>24 MR. FREESE: Move to strike as</p> <p>25 nonresponsive.</p>	<p style="text-align: right;">Page 469</p> <p>1 Q. Now, with regard to the 2015 changes</p> <p>2 to the TVT family of IFUs, was any risk information</p> <p>3 added to the IFUs that was not previously discussed</p> <p>4 in the body of TVT and TVT-O published studies?</p> <p>5 MR. FREESE: Object to the form of</p> <p>6 the question.</p> <p>7 THE WITNESS: There was no new real</p> <p>8 risk information.</p> <p>9 BY MR. GAGE:</p> <p>10 Q. Now, you were the medical director</p> <p>11 for the team at Ethicon that was in charge of making</p> <p>12 these changes to the IFUs; correct?</p> <p>13 A. Yes.</p> <p>14 Q. And over the course of your years,</p> <p>15 have you had an occasion to interact with physicians</p> <p>16 who were actually using the TVT family of devices?</p> <p>17 A. Many.</p> <p>18 Q. Would the same hold true for other</p> <p>19 members of your team?</p> <p>20 A. Of the Health Canada team?</p> <p>21 Q. Yes.</p> <p>22 A. Most of the interactions would have</p> <p>23 come through either the quality people or medical</p> <p>24 affairs.</p> <p>25 Q. Did the team reach any conclusions as</p>

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<p>1 it was going through the analysis of the TVT IFUs as 2 to what doctors may have already known or didn't 3 already know about the substance of the 2015 4 changes? 5 MR. FREESE: Object to the form of 6 the question. 7 THE WITNESS: Yes. 8 BY MR. GAGE: 9 Q. What were those conclusions? 10 A. For the most part -- for the most 11 part, the conversations that I personally had and 12 that we had during our validations of the new IFU 13 was that this is not really new information. 14 Q. And why is that? 15 A. The device is used for the treatment 16 of urinary incontinence. Most of the warnings, most 17 of the adverse events, are events that happened with 18 any method of trying to treat urinary stress 19 incontinence, and the surgeons who were using this 20 understood that for the most part. 21 The other piece of it was that this 22 was a mesh product, and doctors understand what can 23 happen when you put mesh in. 24 MR. FREESE: Move to strike; 25 nonresponsive.</p>	<p>1 practice to make that record or document? 2 A. Yes. 3 Q. Now, sir, if you look under the 4 purpose paragraph there, it says to comply with 5 request from Health Canada to align with the FDA 6 proposed rules and to align with internal standards, 7 change project, certain number, will revise IFUs of 8 products in the TVT product family. This memo 9 serves as the initial product risk assessment 10 evaluating the impact of this change. 11 Do you see that? 12 A. Yes. 13 Q. And then we go further down and it 14 says assessment. 15 A. Yes. 16 Q. Now, this document pertains to the 17 changes to the IFU that were being made in response 18 to Health Canada; correct? 19 A. Yes. 20 Q. We go further down and it says, 21 assessment: Per the design change notice for this 22 project, the proposed IFU changes consist of 23 enhancing the current IFUs to better describe known 24 product risks or to include hazards not currently 25 identified in the IFUs.</p>
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<p>1 BY MR. GAGE: 2 Q. Dr. Weisberg, I'm handing you a 3 document that's been previously marked as P-1635. 4 Are you familiar with this document? 5 A. I am. 6 Q. This appears to be a memo from Lee 7 Hackman to the project file, and the subject says 8 initial product risk assessment for IFU change 9 project for TVT products, and it's dated September 10 19, 2014; correct? 11 A. Correct. 12 Q. Are you familiar with this document? 13 A. I am. 14 Q. Was this document created by a member 15 of your team that was working on the Health Canada 16 response? 17 A. Yes. 18 Q. Was this a writing made at or near 19 the time of the events described in the document by 20 a person or persons with actual knowledge? 21 A. Yes. 22 Q. Was the writing made in the regular 23 course of Ethicon's business? 24 A. Yes. 25 Q. Was it Ethicon's regular business</p>	<p>1 Do you see that? 2 A. Yes. 3 Q. What does that mean? 4 MR. FREESE: Object to the form of 5 the question. 6 THE WITNESS: Well, there is a -- a 7 procedure that we need to follow when we make these 8 changes to see if they were included in the previous 9 risk documents that we created, and one of the 10 things that it looks for is to make sure that all 11 the identified harms are addressed in those risk 12 documents and that to see whether there are any 13 things in the IFU that haven't been addressed. 14 BY MR. GAGE: 15 Q. So we go to the next paragraph and it 16 says, a review of the risk assessment summaries for 17 TVT and TVT Exact and for TVT Obturator and TVT 18 Abbrevio, as well as the corresponding clinical 19 evaluation report for TVT products, confirms that 20 all identified harms are adequately addressed in 21 current risk management documents and that the 22 proposed IFU changes introduce no new design or 23 user-related risks, nor increase any risk levels. 24 Do you see that? 25 A. That's true.</p>

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<p>1 Q. What does it mean when the sentence</p> <p>2 says, a review of the risk assessment summaries</p> <p>3 confirms that all identified harms are adequately</p> <p>4 addressed in current risk management documents?</p> <p>5 MR. FREESE: Object to the form of</p> <p>6 the question.</p> <p>7 THE WITNESS: Risk management</p> <p>8 documents include, among other things, failure mode</p> <p>9 analyses, design failure mode analyses, production</p> <p>10 failure mode analyses, the users -- things that</p> <p>11 could go wrong when the user uses the device,</p> <p>12 application failure mode analyses.</p> <p>13 And for every one of those failure</p> <p>14 modes, anything that could go wrong, we assess what</p> <p>15 the severity of that might be, does it require no</p> <p>16 treatment, does a patient die, and everything in</p> <p>17 between are all given numbers.</p> <p>18 And then we assess the frequency of</p> <p>19 these failure modes and how often they are --</p> <p>20 initially, when a device first comes out, how often</p> <p>21 they are expected to happen and then as they are</p> <p>22 reviewed, how often do they actually happen.</p> <p>23 So you have frequency and severity of</p> <p>24 each hazard and the harm that it may create.</p> <p>25 BY MR. GAGE:</p>	<p>1 to those concepts?</p> <p>2 MR. FREESE: Object to the form of</p> <p>3 the question.</p> <p>4 THE WITNESS: That the ones that were</p> <p>5 in these files remained accurate and honest and none</p> <p>6 had to be changed.</p> <p>7 MR. FREESE: Move to strike as</p> <p>8 nonresponsive.</p> <p>9 - - -</p> <p>10 (Deposition Exhibit No. D-2, 7/29/14</p> <p>11 CAPA-003474, ETH.MESH.22625140 through</p> <p>12 ETH.MESH.22625145, was marked for</p> <p>13 identification.)</p> <p>14 - - -</p> <p>15 BY MR. GAGE:</p> <p>16 Q. Dr. Weisberg, I'm now handing you a</p> <p>17 document marked D-2. Do you see this document?</p> <p>18 A. I do.</p> <p>19 Q. Are you familiar with this document?</p> <p>20 A. I am.</p> <p>21 Q. Is this document, was it created in</p> <p>22 connection with the response to Health Canada?</p> <p>23 A. Yes.</p> <p>24 Q. What is this document?</p> <p>25 A. This is a CAPA report and --</p>
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<p>1 Q. And what did that review conclude</p> <p>2 with regard to the changes being made in response to</p> <p>3 the Health Canada inquiry?</p> <p>4 MR. FREESE: Object to the form of</p> <p>5 the question.</p> <p>6 THE WITNESS: Everything in the</p> <p>7 changes were previously addressed in these failure</p> <p>8 mode analyses.</p> <p>9 MR. FREESE: Move to strike as</p> <p>10 nonresponsive.</p> <p>11 BY MR. GAGE:</p> <p>12 Q. The sentence then goes on: The</p> <p>13 proposed IFU changes introduce no new design or</p> <p>14 user-related risks, nor increase any risk levels.</p> <p>15 What does that mean?</p> <p>16 MR. FREESE: Object to the form of</p> <p>17 the question.</p> <p>18 THE WITNESS: Well, new design or</p> <p>19 user-related risks would be additional things in the</p> <p>20 hazard column of this report, and the risk levels</p> <p>21 would -- would -- the risk level's a summary of the</p> <p>22 severity and the frequency.</p> <p>23 BY MR. GAGE:</p> <p>24 Q. And what was the conclusion, if any,</p> <p>25 of the review of the risk of summaries with regard</p>	<p>1 Q. Let me stop you there. What is a</p> <p>2 CAPA report?</p> <p>3 A. It's a corrective action -- oh, I</p> <p>4 always forget the --</p> <p>5 Q. Is it pre --</p> <p>6 A. Corrective and preventative action --</p> <p>7 Q. All right.</p> <p>8 A. -- report and if something comes up</p> <p>9 that sounds like it might need a corrective or</p> <p>10 preventative action, a CAPA is established and</p> <p>11 investigation is done to see if or whether or what</p> <p>12 may need to be modified to address the issue.</p> <p>13 Q. All right. On the first page, it</p> <p>14 says the CAPA was created July 29, 2014. Do you see</p> <p>15 that?</p> <p>16 A. I see that.</p> <p>17 Q. Was this a writing that was made at</p> <p>18 or near the time of the events described in the</p> <p>19 document by a person or persons with actual</p> <p>20 knowledge?</p> <p>21 A. Yes.</p> <p>22 Q. Was this writing made in the regular</p> <p>23 course of Ethicon's business?</p> <p>24 A. Yes.</p> <p>25 Q. And was it Ethicon's regular business</p>

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<p>1 practice to make this sort of record or document?</p> <p>2 A. Yes.</p> <p>3 Q. Sir, on the first page, we see in the</p> <p>4 middle, it says: This CAPA was open to address the</p> <p>5 labeling updates that will be made to the TVT,</p> <p>6 Gynemesh, and Artisyn product families to address</p> <p>7 the Health Canada Section 39 request.</p> <p>8 Do you see that?</p> <p>9 A. I see that.</p> <p>10 Q. And that's the team that you were the</p> <p>11 medical director for; correct?</p> <p>12 A. Yes.</p> <p>13 Q. On the next page, ETH.MESH.22625141,</p> <p>14 in the middle of the page, we see a paragraph that</p> <p>15 begins: According to the health hazard evaluation,</p> <p>16 HHE, documented in PRE14-0055S, no immediate or</p> <p>17 long-range health consequences that may result from</p> <p>18 use of or exposure to the products are expected.</p> <p>19 The safety and effectiveness of the devices have not</p> <p>20 changed. The existing labels were adequate to</p> <p>21 provide instructions for use including warnings and</p> <p>22 precautions, and the proposed new labels clarify and</p> <p>23 expand on information currently contained within the</p> <p>24 labeling. According to the medical director, quote,</p> <p>25 it is my medical opinion that the existing labels</p>	<p>1 the question.</p> <p>2 THE WITNESS: It was my opinion</p> <p>3 because upon reading it, I felt that anyone who knew</p> <p>4 how to do this procedure would know who to choose to</p> <p>5 do it -- who to choose to do it on, who not to do it</p> <p>6 on, exactly how to do it, and there would have been</p> <p>7 none of the -- well, let me just stop it there.</p> <p>8 BY MR. GAGE:</p> <p>9 Q. All right.</p> <p>10 It says -- it says, although perhaps</p> <p>11 they were not articulated in the manner and to the</p> <p>12 degree requested by Health Canada. Do you see that?</p> <p>13 A. I do.</p> <p>14 Q. What did that mean?</p> <p>15 MR. FREESE: Object to the form of</p> <p>16 the question.</p> <p>17 THE WITNESS: Judging by their</p> <p>18 suggestions, they wanted some very basic,</p> <p>19 well-known, well understood facts to be put into the</p> <p>20 IFU, which were just so well-known in the surgical</p> <p>21 community that they weren't necessarily -- they</p> <p>22 weren't necessary to be there.</p> <p>23 MR. FREESE: Move to strike as</p> <p>24 nonresponsive.</p> <p>25 - - -</p>
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<p>1 were adequate to provide instructions for use</p> <p>2 including warnings and precautions, although perhaps</p> <p>3 they were not articulated in the manner and to the</p> <p>4 degree requested by Health Canada. Changes will be</p> <p>5 made to generally refresh the labels and satisfy</p> <p>6 requests made by Health Canada, close quote.</p> <p>7 Do you see that?</p> <p>8 A. I do.</p> <p>9 Q. It says according to the medical</p> <p>10 director. Who is that person?</p> <p>11 A. That would have been me.</p> <p>12 Q. Are those your words --</p> <p>13 A. Oh. I believe these are my words and</p> <p>14 I believe that was me, yes.</p> <p>15 Q. And that -- the words would be what's</p> <p>16 inside the quotations; correct?</p> <p>17 A. Yes.</p> <p>18 Q. Now, it says, it's my medical opinion</p> <p>19 that the existing labels were adequate to provide</p> <p>20 instructions for use including warnings and</p> <p>21 precautions.</p> <p>22 Do you see that?</p> <p>23 A. Yes.</p> <p>24 Q. Why was that your opinion?</p> <p>25 MR. FREESE: Object to the form of</p>	<p>1 (Deposition Exhibit No. D-3, 2008 TVT</p> <p>2 Brochure, ETH.MESH.08003279 through</p> <p>3 ETH.MESH.08003294, was marked for</p> <p>4 identification.)</p> <p>5 - - -</p> <p>6 BY MR. GAGE:</p> <p>7 Q. Sir, I'm handing you a document</p> <p>8 marked D-3. Are you familiar with this document,</p> <p>9 sir?</p> <p>10 A. Yes, I am.</p> <p>11 Q. And what is this document?</p> <p>12 A. This is a patient brochure.</p> <p>13 Q. And I think if we go over to the last</p> <p>14 page, the very last page near the bottom --</p> <p>15 A. Yes.</p> <p>16 Q. -- it says Ethicon, Inc. 2008. Do</p> <p>17 you see that?</p> <p>18 A. Yes.</p> <p>19 Q. And then it says TVT016R9. What is</p> <p>20 that number?</p> <p>21 A. It's a copy review number.</p> <p>22 Q. And what's the significance, if any,</p> <p>23 of that?</p> <p>24 A. Everything that goes out of Ethicon</p> <p>25 to customers or to patients needs to be reviewed by</p>

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<p>1 medical, legal, and regulatory for accuracy, and 2 that's done by a copy review team; and each of these 3 has a number and that's how you can reference that 4 it was approved. 5 Q. All right. And is this a patient 6 brochure? 7 A. It is a patient brochure. 8 Q. For the TVT family of products? 9 A. Yes. 10 Q. Sir, if you would, turn with me to 11 page 10 -- I'm sorry -- page -- page 13. 12 A. (Witness complies.) 13 Q. Are you at the place where it says: 14 What are the risks? 15 A. Yes. 16 Q. It says: All surgical complications 17 present some risks. Complications associated with 18 the procedure include injury to blood vessels of the 19 pelvis, difficulty urinating, pain, scarring, pain 20 with intercourse, bladder, and bowel injury. 21 There's also a risk of the mesh material becoming 22 exposed. Exposure may require treatment. For a 23 complete description of risks, see the attached 24 product information. Synthetic mesh is a permanent 25 medical device implant; therefore, you should</p>	<p>1 the time of the events described in the document by 2 persons or a team with actual knowledge? 3 A. Yes. 4 Q. And was this writing made in the 5 regular course of Ethicon's business? 6 A. Yes. 7 Q. And was it Ethicon's regular business 8 practice to make those types of records or 9 documents? 10 A. Yes. 11 Q. All right. 12 Sir, I've handed you another 13 document. It's marked D-4. Do you see that? 14 A. Yes. 15 Q. And if you would, what is this 16 document? 17 A. This is also a patient brochure. 18 Q. All right. 19 And we see at the very bottom on the 20 first page, Ethicon, Inc. 2012 and then we see over 21 to the right, TVT-375-12. 22 Do you see that? 23 A. Yes -- yes. 24 Q. And would that be a copy review 25 number?</p>
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<p>1 carefully discuss the decision to have surgery with 2 your doctor and understand the benefits and risks of 3 mesh implant surgery before deciding how to treat 4 your condition. 5 Do you see that? 6 A. Yes. 7 Q. What is the significance, if any, of 8 the risks contained in this 2008 patient brochure in 9 the context of the information that Health Canada 10 was asking you to include in your IFUs? 11 MR. FREESE: Object to the form of 12 the question. 13 THE WITNESS: A good deal of it is 14 within those two paragraphs. 15 - - - 16 (Deposition Exhibit No. D-4, 2012 TVT 17 Brochure, ETH.MESH.09744858 through 18 ETH.MESH.09744863, was marked for 19 identification.) 20 - - - 21 BY MR. GAGE: 22 Q. Sir, I'm handing you a document 23 marked as D-4 -- oh, and I'll tell you what, let me 24 -- let me go back for D-3. 25 Was this a document made at or near</p>	<p>1 A. Yes. 2 Q. And, sir, again, this is a patient 3 brochure for the TVT family of products; is that 4 correct? 5 A. It is. 6 Q. And if you would, sir, please turn to 7 the last piece of paper in this exhibit. 8 A. (Witness complies.) 9 Q. And there's a title -- a heading 10 there that says what are the risks. Do you see 11 that? 12 A. Yes. 13 Q. It says, risks common to all pelvic 14 surgeries: Risks for all pelvic surgeries include 15 pain with intercourse, pelvic pain, development of 16 urinary incontinence or voiding difficulties, 17 hemorrhage, bleeding or hematoma, collections of 18 blood in the pelvis, injury to abdominal organs 19 including bowel, urinary tract infection, bladder 20 injury, wound healing problems, fistula, holes 21 between bladder or bowel and the vagina, injury to 22 ureters, tubes bringing urine from kidneys to 23 bladder, pelvic abscess formation, and nerve damage. 24 Did I read that correctly? 25 A. Yes.</p>

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<p>1 Q. Beneath that, it says, complications 2 associated with synthetic mesh: There is a risk of 3 the mesh material becoming exposed into the vagina. 4 Mesh exposure can be associated with pain during 5 intercourse for you and your partner. Exposure may 6 require treatment, such as vaginal medication or 7 removal of the exposed mesh, which may be performed 8 in the office or operating room. There's a risk of 9 infection, inflammation, vaginal scarring, and mesh 10 contracture, mesh shortening due to scar tissue. 11 Pelvic pain or pain with intercourse may occur and 12 may resolve with time. There is a risk of 13 developing urinary incontinence or difficulty 14 urinating. Synthetic mesh is a permanent medical 15 device implant; therefore, you should carefully 16 discuss the decision to have surgery with your 17 surgeon and understand the benefits and risks of 18 mesh implant surgery before deciding how to treat 19 your condition. 20 Did I read that correctly? 21 A. Yes. 22 Q. Did the Health Canada team, as it was 23 contemplating the requests from Health Canada, take 24 into account any of the information in this patient 25 brochure?</p>	<p>1 Q. Was the writing made in the regular 2 course of Ethicon's business? 3 A. Yes. 4 Q. And was it Ethicon's regular business 5 practice to make records and documents of this type? 6 A. Yes. 7 - - - 8 (Deposition Exhibit No. D-5, 1/15 9 E-Mail Chain, ETH.MESH.22631008, was 10 marked for identification.) 11 - - - 12 BY MR. GAGE: 13 Q. I'm handing you a document marked 14 D-5, and this appears to be an e-mail; is that 15 correct? 16 A. Series of e-mails. 17 Q. Series of e-mails. It's from -- 18 reading from the top of the document down, it's from 19 Stacy Kluesner to Becky Robinson and others, dated 20 January 21, 2015. 21 Do you see that? 22 A. That's correct, yes. 23 Q. And who is Stacy Kluesner? 24 A. Stacy Kluesner is the regulatory 25 representative working on the Health Canada project.</p>
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<p>1 A. Yes. 2 MR. BARLOW: Object to the form and 3 foundation. 4 MR. FREESE: Object to the form of 5 the question. 6 BY MR. GAGE: 7 Q. In what respect? 8 A. We reviewed it. 9 MR. BARLOW: Same objection. 10 BY MR. GAGE: 11 Q. And what is the significance, if any, 12 of the conditions or risks listed in this patient 13 brochure and the requests that Health Canada had 14 made of the company? 15 MR. FREESE: Object to the form of 16 the question. 17 THE WITNESS: Most of the -- the 18 requests by Health Canada are already in the patient 19 brochure. 20 BY MR. GAGE: 21 Q. And was this brochure or writing made 22 at or near the time of the events described in the 23 document by a person or persons with actual 24 knowledge? 25 A. Yes.</p>	<p>1 Q. And so she was one of your team 2 members? 3 A. Yes. 4 Q. Did you work with her in preparing 5 the response to Health Canada? 6 A. Yes. 7 Q. Did you have any conversations with 8 Ms. Kluesner in preparing for your -- in preparing 9 for this deposition? 10 A. I did. 11 Q. What was the purpose of that? 12 A. I just wanted to make sure that my 13 timeline was accurate and that I understood all of 14 her correspondence that I had access to and that I 15 -- I understood some of the regulatory things that 16 may have been happening outside of my purview. 17 Q. And was this a document that you 18 reviewed in preparation for your deposition today? 19 A. Yes. 20 Q. And was this a writing made at or 21 near the time of the events described in the 22 document by a person or persons with knowledge? 23 A. Yes. 24 Q. Was the writing made in the regular 25 course of Ethicon's business?</p>

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<p>1 A. Yes.</p> <p>2 Q. And was it Ethicon's regular business</p> <p>3 practice to make records or documents of this type?</p> <p>4 A. Yes.</p> <p>5 Q. We see -- if we kind of read from the</p> <p>6 bottom up, we see the -- there's an e-mail -- well,</p> <p>7 from the very bottom, there's a Cisco Unity</p> <p>8 Connection Messaging System to</p> <p>9 ehb@fdsla04029.fda.hhs.gov.</p> <p>10 Do you see that?</p> <p>11 A. I do.</p> <p>12 Q. And the subject is message from</p> <p>13 unknown sender. Do you see that?</p> <p>14 A. Yes.</p> <p>15 Q. Do you understand this to be a voice</p> <p>16 mail?</p> <p>17 A. I do.</p> <p>18 Q. And it's dated Monday, January 19,</p> <p>19 2015; correct?</p> <p>20 A. Yes.</p> <p>21 Q. And then we go above and we see an</p> <p>22 e-mail from Elaine Blyskun --</p> <p>23 A. Yes.</p> <p>24 Q. -- at FDA to Stacy Kluesner. Do you</p> <p>25 see that?</p>	<p>1 our final document on what we were going to send to</p> <p>2 Health Canada and the changes we were going to make</p> <p>3 in our IFU, we decided that we should make these</p> <p>4 changes universally or globally.</p> <p>5 And Stacy called the FDA to discuss</p> <p>6 these changes that we were going to make and get</p> <p>7 their blessings that it would be either an</p> <p>8 add-to-file or whether it would need a 510(k)</p> <p>9 application.</p> <p>10 BY MR. GAGE:</p> <p>11 Q. Did FDA first contact Ethicon about</p> <p>12 making changes to the IFUs in the TVT brochures or</p> <p>13 did Ethicon first contact FDA about the changes?</p> <p>14 MR. FREESE: Object to the form of</p> <p>15 the question. You gotta give me a chance to</p> <p>16 interject.</p> <p>17 THE WITNESS: I'm sorry.</p> <p>18 MR. FREESE: So the court reporter</p> <p>19 can get the order correctly.</p> <p>20 THE WITNESS: I'm sorry.</p> <p>21 MR. FREESE: That's okay.</p> <p>22 THE WITNESS: Ethicon made the first</p> <p>23 request to FDA, not the other way around.</p> <p>24 BY MR. GAGE:</p> <p>25 Q. At any time, did FDA ask Ethicon to</p>
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<p>1 A. Yes.</p> <p>2 Q. And it says: Hi, Stacy. I'm sorry</p> <p>3 that I missed your call. I'm currently on detail to</p> <p>4 a different office in CDRH and think it would be</p> <p>5 best if you work with Sharon Andrews and Becky</p> <p>6 Robinson copied here. Thank you, Elaine.</p> <p>7 And then above that, we see an e-mail</p> <p>8 from Ms. Kluesner; correct?</p> <p>9 A. Correct.</p> <p>10 Q. Dear Ms. Robinson and Ms. Andrews, I</p> <p>11 would like to briefly discuss planned labeling</p> <p>12 changes to Ethicon's stress urinary incontinence and</p> <p>13 pelvic organ prolapse devices and updating Ethicon's</p> <p>14 510(k)'s with an add-to-file for these changes.</p> <p>15 Would you have time for a brief discussion, 15</p> <p>16 minutes, in the near future? If so, please let me</p> <p>17 know a time that will be convenient for you.</p> <p>18 Do you see that?</p> <p>19 A. Yes.</p> <p>20 Q. What was -- what did Ethicon do with</p> <p>21 respect to the FDA after it had made the changes</p> <p>22 requested by Health Canada?</p> <p>23 MR. FREESE: Object to the form of</p> <p>24 the question.</p> <p>25 THE WITNESS: When we came up with</p>	<p>1 implement the Health Canada changes in the United</p> <p>2 States?</p> <p>3 MR. FREESE: Object to the form of</p> <p>4 the question.</p> <p>5 THE WITNESS: No.</p> <p>6 BY MR. GAGE:</p> <p>7 Q. What was your team's understanding,</p> <p>8 if any, as to whether Ethicon was going to be</p> <p>9 required to implement these changes in the United</p> <p>10 States?</p> <p>11 MR. FREESE: Object to the form of</p> <p>12 the question.</p> <p>13 THE WITNESS: We had no indication</p> <p>14 that they would be required.</p> <p>15 BY MR. GAGE:</p> <p>16 Q. Did Ethicon act on its own volition</p> <p>17 to implement these changes in the United States?</p> <p>18 MR. FREESE: Object to the form of</p> <p>19 the question.</p> <p>20 THE WITNESS: Yes.</p> <p>21 BY MR. GAGE:</p> <p>22 Q. When FDA was contacted by Ethicon</p> <p>23 about the 2015 changes to the IFU and brochure, did</p> <p>24 FDA ever indicate that it was going to order or</p> <p>25 otherwise require Ethicon to implement these</p>

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<p>1 changes?</p> <p>2 A. No.</p> <p>3 - - -</p> <p>4 (Deposition Exhibit No. D-6, 4/8/15</p> <p>5 Cover Letter from Kluesner Attaching</p> <p>6 Add-To-File Submission, etc., Beginning</p> <p>7 with ETH.MESH.22617620, was marked for</p> <p>8 identification.)</p> <p>9 - - -</p> <p>10 BY MR. GAGE:</p> <p>11 Q. Dr. Weisberg, at some point in time,</p> <p>12 did Ethicon provide any documentation to FDA about</p> <p>13 the proposed changes to the IFUs and brochures in</p> <p>14 the United States?</p> <p>15 A. Yes.</p> <p>16 Q. Dr. Weisberg, I'm handing you a</p> <p>17 document that's been marked as D-6. Take just a</p> <p>18 minute and look at that.</p> <p>19 A. (Witness complies.) Okay.</p> <p>20 Q. Now, Doctor, what is collectively</p> <p>21 marked as D-6 is one, two, three, four, five, six</p> <p>22 different separately stapled groups of documents;</p> <p>23 correct?</p> <p>24 A. Yes.</p> <p>25 Q. And the first one is dated April 8,</p>	<p>1 IFUs as they were and as we intend to change them.</p> <p>2 And they were submitted to the FDA for examination.</p> <p>3 Q. And when you say redlined documents,</p> <p>4 what do you mean by redlined?</p> <p>5 A. Well, on a computer, if you delete</p> <p>6 something, the red line goes through it to delete it</p> <p>7 and if you add something, a red line goes under that</p> <p>8 addition, so you can readily look at it and see what</p> <p>9 was deleted and what was added.</p> <p>10 Q. And what was the purpose of sending</p> <p>11 these to the -- of your team sending these to the</p> <p>12 FDA?</p> <p>13 A. We wanted them to know what kind of</p> <p>14 changes we were intending to make.</p> <p>15 - - -</p> <p>16 (Deposition Exhibit No. D-7, E-Mail</p> <p>17 Chain and Attachments, Beginning with</p> <p>18 ETH.MESH.22865906, was marked for</p> <p>19 identification.)</p> <p>20 - - -</p> <p>21 BY MR. GAGE:</p> <p>22 Q. Dr. Weisberg, I'm handing you a</p> <p>23 document marked D-7. Are you familiar with this</p> <p>24 document?</p> <p>25 A. I am.</p>
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<p>1 2015 and the re line is add-to-file submission,</p> <p>2 Gynecare TVT system; correct?</p> <p>3 A. Yes.</p> <p>4 Q. And the next one is another</p> <p>5 add-to-file submission; correct?</p> <p>6 A. Yes.</p> <p>7 Q. In fact, each one of these separately</p> <p>8 stapled documents is a separate add-to-file</p> <p>9 submission; is that correct?</p> <p>10 A. That's correct.</p> <p>11 Q. Now, were these documents,</p> <p>12 collectively marked as Exhibit D-6, writings that</p> <p>13 were made at or near the time of the events</p> <p>14 described in the documents by a person or persons</p> <p>15 with actual knowledge?</p> <p>16 A. Yes.</p> <p>17 Q. Were these writings made in the</p> <p>18 regular course of Ethicon's business?</p> <p>19 A. Yes.</p> <p>20 Q. And was it Ethicon's regular business</p> <p>21 practice to make these records and documents?</p> <p>22 A. Yes.</p> <p>23 Q. What are these documents?</p> <p>24 A. These are add-to-file submissions,</p> <p>25 meaning they are basically redlined documents of the</p>	<p>1 Q. And this is a chain of e-mails which</p> <p>2 on the first page at the top is from Stacy Kluesner</p> <p>3 dated June 1, 2015 to Sharon Andrews, re: Ethicon</p> <p>4 510(k) amendments for labeling changes request for</p> <p>5 redline patient labeling.</p> <p>6 Did I read that correctly?</p> <p>7 A. Yes, you did.</p> <p>8 Q. And we -- the e-mail chain continues</p> <p>9 a little bit, but at the top on the first page, it</p> <p>10 says: Good afternoon, Sharon -- this is the e-mail</p> <p>11 from Stacy to Sharon -- it says, Good afternoon,</p> <p>12 Sharon. As per the FDA's request, we're providing</p> <p>13 the redlines for the TVT family of products patient</p> <p>14 brochure and the Artisyn Y patient brochure to</p> <p>15 support the previously submitted add-to-files.</p> <p>16 Thank you for your continued support during the</p> <p>17 add-to-file review. Please feel free to contact me</p> <p>18 if the agency has any additional questions.</p> <p>19 Sincerely, Stacy.</p> <p>20 Did I read that correctly?</p> <p>21 A. You did and it reminds thee that I</p> <p>22 should probably amplify my previous answer about why</p> <p>23 we sent the redlines.</p> <p>24 It's true that we wanted them to see</p> <p>25 the changes, but I do remember now that in the</p>

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<p>1 conversation, FDA said can you send us some redline 2 changes. 3 MR. FREESE: Move to strike as 4 nonresponsive. 5 MR. GAGE: Why did you send redline 6 versions of the IFUs and the patient brochures to 7 the FDA? 8 THE WITNESS: Well, this reminded me 9 that the FDA did ask for them. 10 BY MR. GAGE: 11 Q. All right. So going back to the -- 12 7, what document is being sent to FDA here? 13 A. This is a patient brochure. 14 Q. And I see handwriting -- they're two 15 different brochures; correct? 16 A. Yes. 17 Q. And I think if you go to -- if you go 18 a little deeper into the document, flip with me to 19 ETH.MESH.24255174 -- do you see that? 20 A. Yes. 21 Q. -- it's a -- this appears to be the 22 first page of the Gynecare TVT family of products 23 patient brochure? 24 A. Yes. 25 Q. All right.</p>	<p>1 A. I was. 2 Q. And was this document -- was this 3 document and the attachments, were these made at or 4 near the time of the events described in the 5 document by a person or persons with actual 6 knowledge? 7 A. Yes. 8 Q. Was the writing made in the regular 9 course of Ethicon's business? 10 A. Yes. 11 Q. And was it Ethicon's regular business 12 practice to make this record or document? 13 A. Yes. 14 - - - 15 (Deposition Exhibit No. D-8, 6/4/15 16 E-Mail from Andrews to Kluesner, 17 ETH.MESH.22634691 and ETH.MESH.22634692, 18 was marked for identification.) 19 - - - 20 BY MR. GAGE: 21 Q. Dr. Weisberg, I'm handing you a 22 document marked D-8. This appears to be an e-mail 23 from Sharon Andrews to Stacy Kluesner, and it's re a 24 number of specific documents. And the subject line 25 is physician and patient labeling updates to Ethicon</p>
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<p>1 And we see handwritten changes 2 throughout this document. 3 A. Yes. 4 Q. Correct? 5 A. Correct. 6 Q. And then at the back, we see -- 7 actually 242 -- ETH.MESH.24255186 -- 8 A. Yes. 9 Q. -- we see a typed sheet. Do you see 10 that? 11 A. Yes. 12 Q. All right. 13 And what are these handwritten 14 changes? 15 A. Well, the patient brochure was a 16 printed document that was not editable. So the 17 redlining was done manually, I believe by Stacy 18 Kluesner, to show the changes. 19 Q. And the redline changes, were those 20 changes Stacy herself thought up or were these 21 changes that the team put together? 22 A. These were changes that the team came 23 up with. 24 Q. And you were involved in those 25 changes?</p>	<p>1 urogynecologic surgical mesh, dated June 4, 2015. 2 Do you see that? 3 A. Yes. 4 Q. Are you familiar with this document? 5 A. I am. 6 Q. Did you -- did you discuss it with 7 Stacy Kluesner? 8 A. I did. 9 Q. In preparation for your deposition? 10 A. I did. 11 Q. And, generally, what is this 12 document? 13 A. This is a response from the FDA with 14 some suggestions for the new labeling. 15 Q. All right. So we go down to number 16 1 -- we see number 1, 2, 3 A, B, and C; correct? 17 A. Yes. 18 Q. And in each of these, the FDA -- what 19 is the FDA doing in these various paragraphs? 20 A. They're making suggestions on how 21 these might be edited or changed from what we sent 22 in. 23 Q. And number 1, it says: The physician 24 labeling includes two categories of risks, adverse 25 reactions and other adverse reactions. It is</p>

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<p>1 unclear why the risks identified as other are</p> <p>2 categorized separately from the risks described as</p> <p>3 adverse reactions. We recommend that you revise the</p> <p>4 labeling to combine both categories or explain why</p> <p>5 the criteria used to categorize the risks into</p> <p>6 different categories; correct?</p> <p>7 A. Correct.</p> <p>8 Q. And then it says for the Gynecare TVT</p> <p>9 family of devices, we also note that voiding</p> <p>10 dysfunction is listed under adverse reactions, but</p> <p>11 urge incontinence, urinary frequency, and urinary</p> <p>12 retention, all types of voiding dysfunction, are</p> <p>13 listed as other adverse reactions. We recommend</p> <p>14 that you list incontinence, urgency -- urinary</p> <p>15 frequency, and urinary retention as examples of</p> <p>16 voiding dysfunction under adverse reactions or</p> <p>17 clarify in the physician labeling why urge</p> <p>18 incontinence, urinary frequency, and urinary</p> <p>19 retention are categorized separately under other</p> <p>20 adverse reactions; correct?</p> <p>21 A. Correct.</p> <p>22 Q. And then paragraph 3 has various</p> <p>23 suggestions or recommendations for the patient</p> <p>24 labeling; correct?</p> <p>25 A. Yes.</p>	<p>1 letter.</p> <p>2 BY MR. GAGE:</p> <p>3 Q. Did FDA ever ask or suggest to</p> <p>4 Ethicon that a dear doctor letter was necessary?</p> <p>5 A. No.</p> <p>6 MR. FREESE: Object to the form of</p> <p>7 the question.</p> <p>8 THE WITNESS: I'm sorry.</p> <p>9 MR. FREESE: That's okay. Don't</p> <p>10 worry.</p> <p>11 THE WITNESS: Want to do it again?</p> <p>12 MR. FREESE: That's fine.</p> <p>13 BY MR. GAGE:</p> <p>14 Q. Why didn't Ethicon send a dear doctor</p> <p>15 letter?</p> <p>16 MR. FREESE: Object to the form of</p> <p>17 the question.</p> <p>18 THE WITNESS: Ethicon didn't feel it</p> <p>19 was necessary.</p> <p>20 BY MR. GAGE:</p> <p>21 Q. Why?</p> <p>22 A. Because the existing IFU we felt was</p> <p>23 adequate, and the safety and effectiveness record of</p> <p>24 the device really bolstered that opinion.</p> <p>25 MR. FREESE: Move to strike as</p>
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<p>1 Q. And this was a document received by</p> <p>2 Stacy Kluesner in the course of her employment at</p> <p>3 Ethicon concerning the changes to the TVT and</p> <p>4 Gynemesh IFUs and brochures; correct?</p> <p>5 A. Correct.</p> <p>6 - - -</p> <p>7 (Deposition Exhibit No. D-9, Six-Page</p> <p>8 Document Labeled "Chronology", was marked</p> <p>9 for identification.)</p> <p>10 - - -</p> <p>11 BY MR. GAGE:</p> <p>12 Q. Apart from Exhibit 8, which is the</p> <p>13 e-mail from Sharon Andrews at FDA to Stacy Kluesner,</p> <p>14 did FDA otherwise provide any comments to any of</p> <p>15 Ethicon's proposed changes?</p> <p>16 MR. FREESE: Object to the form of</p> <p>17 the question.</p> <p>18 THE WITNESS: No.</p> <p>19 BY MR. GAGE:</p> <p>20 Q. Did FDA ever object to any of the</p> <p>21 changes that Ethicon proposed to the IFUs or patient</p> <p>22 brochures?</p> <p>23 MR. FREESE: Object to the form of</p> <p>24 the question.</p> <p>25 THE WITNESS: Nothing outside of this</p>	<p>1 nonresponsive.</p> <p>2 BY MR. GAGE:</p> <p>3 Q. At some point, did Ethicon put the</p> <p>4 revised IFUs for the TVT family on the Ethicon</p> <p>5 website?</p> <p>6 A. Yes.</p> <p>7 Q. Can you tell us when, approximately,</p> <p>8 that would have occurred?</p> <p>9 A. Hang on. May 1st, 2015.</p> <p>10 Q. At some point, did Ethicon begin</p> <p>11 putting the revised IFUs in the actual boxes in</p> <p>12 which the products are packaged and shipped to</p> <p>13 customers?</p> <p>14 A. Yes.</p> <p>15 Q. When did that occur?</p> <p>16 A. September -- September-October 2015.</p> <p>17 Q. Dr. Weisberg, I'm handing you a</p> <p>18 document that I'm marking as Exhibit 9. This is a</p> <p>19 chronology that you have referred to several times</p> <p>20 during your testimony; is that correct?</p> <p>21 A. That's correct.</p> <p>22 Q. Is this a document that you helped</p> <p>23 prepare in order for you to be prepared to testify</p> <p>24 at this deposition?</p> <p>25 A. Yes.</p>

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<p>1 Q. Did you review the entries on this 2 timeline?</p> <p>3 A. I did.</p> <p>4 Q. Did you investigate to ensure -- or 5 did you conduct an investigation to ensure that the 6 entries are accurate and correct?</p> <p>7 A. Yes. 8 - - - 9 (Deposition Exhibit No. D-10, 6/5/15 10 E-Mails, with First One from Andrews to 11 Kluesner, ETH.MESH.22865922, was marked 12 for identification.) 13 - - -</p> <p>14 BY MR. GAGE:</p> <p>15 Q. Dr. Weisberg, I'm handing you a 16 collection of e-mails from Sharon Andrews to Stacy 17 Kluesner, all of which are dated June 5, 2015. 18 Do you see those?</p> <p>19 A. Yes.</p> <p>20 Q. And it says: We've reviewed the 21 information sent to your previously closed 22 submission. 23 And then there's a number and the 24 number would be different for each of the various 25 e-mails; correct?</p>	<p>1 Q. What are these generally?</p> <p>2 A. Well, this -- it's a letter of 3 closure from the FDA saying they've reviewed our 4 request and basically approve it.</p> <p>5 Q. Did FDA --</p> <p>6 MR. FREESE: Move to strike as 7 nonresponsive. 8 BY MR. GAGE:</p> <p>9 Q. Did FDA require you to submit a 10 510(k)?</p> <p>11 A. They did not.</p> <p>12 Q. And that would hold true with regard 13 to any of the devices or IFUs or patient brochures 14 that we've been discussing?</p> <p>15 A. Yeah, in these applications, yes. 16 (Pause.)</p> <p>17 BY MR. GAGE:</p> <p>18 Q. Dr. Weisberg, I'm handing you a 19 document that was marked yesterday as P-1638. It's 20 the transcript of Piet Hinoul dated January 14, 21 2014, and I'm opening it to the page that I'd like 22 for you to be looking at. It's actually page 1244. 23 MS. KABBASH: You know what? 24 THE WITNESS: Okay. Do you need 25 this?</p>
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<p>1 A. Yes.</p> <p>2 MR. FREESE: Is this D-10? Okay. Go 3 ahead. You're good.</p> <p>4 BY MR. GAGE:</p> <p>5 Q. Then on the first e-mail that's part 6 of the collective Exhibit D-10, it says June 5, 7 2015: Based solely on the information you have 8 provided, it does not appear that you have 9 significantly changed or modified the design, 10 components, method of manufacture, or intended use 11 of the device. Additionally, we did not review any 12 data submitted with this add-to-file. It is, 13 however, your responsibility to determine if the 14 change or modification to the device or its labeling 15 could significantly affect the device's safety or 16 effectiveness and thus requiring submission of a new 17 510(k). Please refer to the guidance in deciding 18 when to submit a 510(k) for a change to an existing 19 device at -- and then there's a website provided. 20 And then it says: The information 21 you have supplied will be added to your submission 22 record, and then it indicates that the particular 23 file number is now closed. 24 Did I read that correctly? 25 A. Yes.</p>	<p>1 MR. FREESE: Yes, sir. 2 (Pause.)</p> <p>3 MR. FREESE: Is this the page we're 4 looking at?</p> <p>5 MR. GAGE: Yeah.</p> <p>6 MR. FREESE: Did you mark this 7 already? It's P --</p> <p>8 MR. GAGE: It's already marked.</p> <p>9 THE WITNESS: 1638.</p> <p>10 MR. GAGE: P-1638.</p> <p>11 BY MR. GAGE:</p> <p>12 Q. Dr. Weisberg, you were asked some 13 questions about some of Dr. Hinoul's previous 14 deposition testimony yesterday. Do you remember 15 that?</p> <p>16 A. Yes.</p> <p>17 Q. And who is Dr. Hinoul?</p> <p>18 A. Dr. Hinoul is a urogynecologist 19 currently working as the chief medical officer in 20 Ethicon.</p> <p>21 Q. And you are -- do you know Dr. 22 Hinoul?</p> <p>23 A. Yes.</p> <p>24 Q. And on page 24, line 8, there's a 25 line of questioning that I'd like to just refresh</p>

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<p>1 your recollection about. It was question: One of</p> <p>2 the known adverse events is clinically significant</p> <p>3 compression -- rephrase. One of the known adverse</p> <p>4 events is what is termed as contraction of the mesh;</p> <p>5 correct? Answer: I disagree with that.</p> <p>6 Question: Because I called it</p> <p>7 contraction of the mesh. Answer: Correct.</p> <p>8 Question: One of the known adverse events is</p> <p>9 contraction; correct? Answer: Contraction of the</p> <p>10 tissue around the mesh, yes.</p> <p>11 Question: And we're talking in this</p> <p>12 context of the scar tissue forming around the mesh</p> <p>13 that compresses down and contracts the mesh;</p> <p>14 correct? Answer: Squeeze the mesh so it's</p> <p>15 enveloped in the scar and that is retracted, yes.</p> <p>16 So the total mesh scar, that is what contracts.</p> <p>17 I think I've heard that referred to</p> <p>18 as the scar mesh complex. Answer: That's an</p> <p>19 appropriate way of putting it.</p> <p>20 Did I read that correctly?</p> <p>21 A. Yes.</p> <p>22 Q. Now, you were asked some questions</p> <p>23 about that testimony. Anywhere in this section, is</p> <p>24 there any reference to excessive contraction?</p> <p>25 MR. FREESE: Object to the form of</p>	<p>1 excessive contraction occurs in a TVT device?</p> <p>2 MR. BARLOW: Object to form.</p> <p>3 THE WITNESS: Theoretically, yes.</p> <p>4 BY MR. GAGE:</p> <p>5 Q. What was the evidence, if any, that</p> <p>6 the company had to demonstrate that excessive</p> <p>7 contraction was, in fact, occurring in TVT devices?</p> <p>8 MR. FREESE: Object to the form of</p> <p>9 the question.</p> <p>10 THE WITNESS: Well, I don't know that</p> <p>11 we had any evidence that it was -- that excessive</p> <p>12 contraction was occurring.</p> <p>13 BY MR. GAGE:</p> <p>14 Q. Now, can you explain to the jury</p> <p>15 whether mesh contracts -- and when I say mesh, I'm</p> <p>16 talking about the mesh in -- well, strike that.</p> <p>17 Can you describe for the jury --</p> <p>18 strike that.</p> <p>19 Does mesh contract?</p> <p>20 MR. FREESE: Object to form --</p> <p>21 MR. GAGE: After it's implanted in</p> <p>22 the body?</p> <p>23 MR. FREESE: Object to the form of</p> <p>24 the question.</p> <p>25 THE WITNESS: The mesh itself does</p>
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<p>1 the question.</p> <p>2 THE WITNESS: The word "excessive" is</p> <p>3 not in there.</p> <p>4 BY MR. GAGE:</p> <p>5 Q. Dr. Weisberg, you were asked some</p> <p>6 questions about the response to Health Canada; and I</p> <p>7 believe in the response, there was an indication</p> <p>8 that the IFU would be revised to the TVT family of</p> <p>9 devices -- the IFUs for those products would be</p> <p>10 revised to include a warning or a statement about</p> <p>11 excessive contraction.</p> <p>12 Do you recall those questions?</p> <p>13 A. Yes.</p> <p>14 Q. And, ultimately, did that statement</p> <p>15 about excessive contraction appear in the TVT family</p> <p>16 IFUs?</p> <p>17 A. It did not.</p> <p>18 Q. Why is that?</p> <p>19 A. We couldn't find good evidence that</p> <p>20 it was a truthful statement that, indeed -- first of</p> <p>21 all, excessive was never defined anywhere. Second</p> <p>22 of all, we weren't able to establish a cause and</p> <p>23 effect for contraction and any of the -- the adverse</p> <p>24 events that were reported.</p> <p>25 Q. Is it theoretically possible that</p>	<p>1 not contract. The fibers of the mesh do not</p> <p>2 contract.</p> <p>3 BY MR. GAGE:</p> <p>4 Q. Does scar tissue contract?</p> <p>5 A. Yes.</p> <p>6 MR. FREESE: Object to the form of</p> <p>7 the question.</p> <p>8 BY MR. GAGE:</p> <p>9 Q. What impact, if any, does the</p> <p>10 contraction of scar tissue have on mesh that is near</p> <p>11 it or touching it?</p> <p>12 MR. FREESE: Object to the form of</p> <p>13 the question; outside the scope. Can I have a</p> <p>14 continuing objection on these questions as it being</p> <p>15 outside the scope?</p> <p>16 MR. GAGE: You may.</p> <p>17 MR. FREESE: Because you objected</p> <p>18 that it was outside the scope and so your questions</p> <p>19 are outside the scope, too.</p> <p>20 MR. GAGE: Okay.</p> <p>21 MR. FREESE: Fair enough?</p> <p>22 MR. GAGE: Fair enough.</p> <p>23 MR. BARLOW: Contingent objections.</p> <p>24 MR. GAGE: Contingent scope</p> <p>25 objections.</p>

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<p>1 THE WITNESS: Well, what happens to 2 the mesh when it's implanted is that the tissue from 3 the body -- the body tissues grow into those little 4 holes and really wind up encapsulating the mesh in 5 tissue in and out of the holes and all around it. 6 So if that tissue contracts, it pulls the mesh with 7 it. 8 The mesh itself, the fibers of the 9 mesh, don't contract, but the complex of the scar 10 tissue -- and that's what -- that's what it is. 11 It's a -- it's supposed to be a scarring type of 12 ingrowth; as that contracts, it takes the mesh with 13 it, to some extent. 14 BY MR. GAGE: 15 Q. Is that contraction a good thing or a 16 bad thing? 17 MR. FREESE: Object to the form of 18 the question. 19 THE WITNESS: Well, it's a broad 20 question. Are you referring to TVT? 21 MR. GAGE: Yes. 22 THE WITNESS: In TVT, it's not 23 necessarily a bad thing. In fact, what it does, it 24 helps support the urethra. Now, that's going to 25 require some explanation.</p>	<p>1 grows into the scaffold and then supports the 2 urethra. So a little bit of contraction is good in 3 that case. 4 And we know it happens and that's why 5 we make it loose when we put it in, so that we don't 6 get obstruction. 7 MR. BARLOW: Object as nonresponsive. 8 BY MR. GAGE: 9 Q. All right. 10 Yesterday, during your deposition, 11 you were asked a question and I'm reading from the 12 transcript. It said, question: Excessive 13 contraction or shrinkage of the tissue surrounding 14 the mesh, as we've just discussed it, is that an 15 adverse reaction with the TVT? Correct? Answer: 16 Excessive, yes. 17 And it would be reasonable and 18 feasible to include that in the IFU, particularly 19 the adverse reactions section for the TVT; correct? 20 Answer: It would be reasonable to include it. 21 Question: And it would have been reasonable and 22 feasible to do so right from the beginning when the 23 TVT first went on the market and the first IFU came 24 out; correct? The witness: It would have been 25 reasonable, yes, and feasible.</p>
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<p>1 The TVT works as a loop (Indicating) 2 under the urethra -- 3 MR. FREESE: Hold on one second, 4 Doctor. I object to the form of the question 5 because he asked you a question and you asked again, 6 so, I'm sorry, I object to the form of the question 7 that Dr. Weisberg's answering right now. 8 Go ahead. 9 THE WITNESS: Okay. So one of the 10 problems with incontinence is that the urethra 11 drops, and the purpose of the sling is to go under 12 the urethra and then up out of the way and anchor 13 itself into some kind of tissue. 14 And as the tissue grows into this, it 15 helps support this mesh that we put in and kind of 16 anchors or glues it; and as it contracts, it can -- 17 it contracts a little bit. It doesn't contract a 18 whole lot, because if it did, it would block the 19 urine from coming out and we know that it doesn't do 20 that at the time that the mesh is working its way 21 into the tissue. 22 So what happens is, the -- it 23 essentially makes, like, new ligaments to hold up 24 the urethra. So the mesh is a -- is a -- I'm 25 blanking on the word -- like a scaffold. The tissue</p>	<p>1 Do you wish to clarify that 2 testimony? 3 MR. FREESE: Object to the form of 4 the question. 5 THE WITNESS: Well -- 6 MR. GAGE: Let me ask you this: Are 7 those answers correct? 8 MR. FREESE: Object to the form of 9 the question. 10 THE WITNESS: They won't be correct 11 unless I can explain them. 12 MR. GAGE: Please explain. 13 MR. FREESE: Object to the form of 14 the question. 15 THE WITNESS: And the fact is that 16 since we have no good cause-and-effect evidence that 17 this is an adverse reaction, at this point, I don't 18 think that it would be good to include it. 19 BY MR. GAGE: 20 Q. Who made that decision when the -- 21 when the company was looking at the changes 22 requested by Health Canada? 23 A. I did. 24 Q. Sir, you were asked a question 25 yesterday at your deposition -- and I'll read the</p>

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<p>1 question and answer to you. 2 A. Do I have it here? 3 MS. KABBASH: Actually, you know 4 what? I don't think he does -- 5 MR. GAGE: No, you don't. 6 I don't think I have to mark this as 7 an exhibit because this is just a rough transcript 8 from yesterday, so I'm not going to mark that as an 9 exhibit. 10 But, Dr. Weisberg, I'm handing you a 11 copy of the rough transcript from yesterday's 12 proceedings where you were deposed, and if you could 13 turn to page 183? 14 THE WITNESS: (Witness complies.) 15 BY MR. GAGE: 16 Q. And at the bottom, at line 18, do you 17 see where the question begins, this IFU -- 18 A. Yes. 19 Q. -- question: This IFU does not 20 distinguish between an acute or a chronic foreign 21 body response. It just says that the foreign body 22 response in total is transitory. That is 23 technically incorrect. Right? Objection. The 24 witness: Hang on. Let me look at this. No, it 25 doesn't say that. It says transitory local</p>	<p>1 becomes very clear that these cells are not going to 2 be able to eat this; and in the process of trying to 3 get rid of it, that's an acute foreign body 4 reaction. 5 After a while, when it's clear that 6 it's not going to work, the body in its wisdom sets 7 up kind of a neutral zone where the foreign body 8 reaction isn't working, the acute foreign body 9 reaction isn't working, but it still identifies the 10 fact that the cells of the body are different from 11 the implant. 12 So at the junction, just at the 13 junction, of the implant and the tissue, a different 14 kind of cell comes in and a pathologist or a micro 15 -- not a microbiologist -- a histologist will look 16 under a microscope and say that this is defined by a 17 number of parameters as a chronic foreign body 18 reaction. And that stays for the life of the -- of 19 the device. 20 However, a chronic foreign body 21 reaction does not cause the same kind of body 22 effects that an acute one does. So there might be 23 some inflammation in the beginning when these cells 24 come in, but eventually, these cells and the foreign 25 body coexist.</p>
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<p>1 irritation and -- oh, yes, and a transitory foreign 2 body response may occur. It says it's transitory. 3 Yes. Question: That's technically incorrect 4 because it's chronic; correct? Objection. The 5 witness: Yes. 6 Do you see that? 7 A. I do. 8 Q. Is that a correct answer? 9 MR. FREESE: Object to the form of 10 the question. 11 THE WITNESS: It's really not because 12 I didn't get a chance to explain it. 13 MR. GAGE: Can you explain why your 14 prior answer is really not correct? 15 THE WITNESS: Yes. It's not a yes or 16 no question. It requires explanation. It's going 17 to take me about two minutes to explain what foreign 18 body reaction is and how it works in the body. 19 When anything is implanted, anything, 20 the body tries to get rid of it; and one of the 21 things that it does, it sends in cells to try to eat 22 it, try to destroy it. And some of those cells, 23 depending on what those cells are, are classified 24 under the microscope as a foreign body reaction. 25 With something like polypropylene, it</p>	<p>1 And if -- if you understand what a 2 chronic foreign body reaction is, it's not an 3 inflammatory condition. There are cells that 4 identify it as a foreign body reaction, but, I mean, 5 the way I learned it and the way it's always been is 6 that if you're still having inflammation after two, 7 three weeks of the chronic foreign body reaction, 8 you gotta look for something else like an infection. 9 The chronic foreign body reaction is 10 just there. You can see it on the microscope. The 11 tissue is now working its way into -- into or around 12 this foreign body. It's walling it off -- it can't 13 get rid of it, so it's just walling it off -- and 14 those cells where the tissue meets the foreign body, 15 that's called a chronic foreign body reaction. 16 So it was very difficult to answer 17 that question with a yes or a no. 18 MR. FREESE: Move to strike; 19 nonresponsive. 20 BY MR. GAGE: 21 Q. Sir, if you would, turn to page 49 of 22 your deposition -- I'm sorry. Turn to page 49 of 23 the transcript of yesterday's proceedings when you 24 were deposed. 25 A. (Witness complies.) Okay.</p>

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<p>1 Q. Line 20, there's a question that 2 reads, question: The adverse reactions that are 3 listed in the IFU for each of the devices at issue 4 here are accurate. Right? Objection. The witness: 5 Yeah, accurate, but not all inclusive. 6 Do you see that? 7 A. Correct. 8 Q. What does -- what do you mean by not 9 all inclusive? 10 MR. FREESE: Object to the form of 11 the question. 12 THE WITNESS: Instructions for use 13 tells the doctor what the device is. It tells him 14 when to use it, when not to use it, and lists some 15 adverse reactions. 16 Any adverse reactions that are 17 specific to that device should absolutely be listed; 18 but when you realize that most of the adverse 19 reactions are associated with any kind of surgery 20 for this -- for this problem, you can't possibly -- 21 you don't need to possibly list everything that can 22 go wrong in surgery. 23 It's common knowledge. People 24 understand what can happen in surgery. People 25 understand that surgery hurts. People understand</p>	<p>1 THE WITNESS: Because it was common 2 knowledge to anyone who does this kind of surgery or 3 uses mesh. We knew it. Our consultants knew it. 4 The people who reviewed our IFUs knew it, and 5 basically anybody who's had any medical training 6 knows it. 7 BY MR. GAGE: 8 Q. You were asked a number of times 9 yesterday and today whether it would have been 10 reasonable to warn about certain adverse events at 11 the time the various devices were launched. 12 Do you recall those questions? 13 A. I do. 14 Q. Your answers were yes to most of 15 those. Do you recall that? 16 A. Yes. 17 Q. Was it necessary to include those 18 words in order for the IFUs to be adequate? 19 MR. FREESE: Object to the form of 20 the question. 21 THE WITNESS: No. 22 BY MR. GAGE: 23 Q. Why not? 24 MR. FREESE: Same objection. 25 THE WITNESS: As I mentioned before,</p>
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<p>1 that surgery sometimes needs to be redone. People 2 understand that surgery doesn't always work. 3 And for those reasons and for -- with 4 the line that people who are doing this operation 5 need to understand the treatment of stress 6 incontinence and need to understand how to use this 7 device, most of those things are really superfluous 8 and wouldn't affect the safety or effectiveness of 9 the device. 10 BY MR. GAGE: 11 Q. When you reference people, are you 12 referring to doctors? 13 A. The surgeons who are using the 14 device. 15 Q. Now, Dr. Weisberg, you were asked a 16 number of questions yesterday and today as to 17 whether Ethicon was aware of various risks at the 18 time the device first went on the market. 19 Do you recall those questions? 20 A. Yes. 21 Q. How is it that Ethicon would know 22 what the risks are of the device before the device 23 even goes on the market? 24 MR. FREESE: Object to the form of 25 the question.</p>	<p>1 some of those things -- most of those things -- 2 refer to the general adverse events associated with 3 surgery and/or mesh implantation. 4 BY MR. GAGE: 5 Q. Sir, you were asked a number of 6 questions about the various IFUs and whether they 7 warned of urge incontinence. Do you recall that? 8 A. Yes. 9 Q. And in some instances, the phrase 10 urge incontinence was not found in the IFUs. Do you 11 recall that? 12 A. That's correct. 13 Q. What is detrusor instability? 14 A. It's the medical term for urge 15 incontinence. It also includes frequency. 16 Q. Does the term detrusor instability 17 appear in the IFUs for the TVT family of products? 18 A. Yes. 19 Q. So were your answers correct when you 20 said the IFUs did not warn of urge incontinence? 21 MR. FREESE: Object to the form of 22 the question. 23 THE WITNESS: They were not correct. 24 BY MR. GAGE: 25 Q. Dr. Weisberg, you've answered a</p>

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<p>1 number of questions over the past two days by saying 2 histologically, yes or histologically, that is 3 correct. 4 What do you mean by that? 5 A. Well, I'll refer back to my previous 6 answer about chronic foreign body reaction, which 7 means, under the microscope, you see cells that 8 define chronic foreign body reaction. 9 But chronic foreign body reaction is 10 not something that causes inflammation after its 11 initial -- after the initial cells get in and the 12 coating starts on the foreign body. 13 MR. FREESE: Move to strike; 14 nonresponsive. 15 MR. GAGE: Dr. Weisberg, that's all I 16 have now. 17 MR. FREESE: Let's flip-flop real 18 quick. 19 THE VIDEO TECHNICIAN: The time is 20 3:18. We're going off the record. 21 (A recess was taken from 3:18 p.m. to 22 3:26 p.m.) 23 THE VIDEO TECHNICIAN: The time is 24 3:26. We're back on the record. 25</p>	<p>1 A. I'm paid by the hour, but limited to 2 a number of hours. 3 Q. And all the time for your preparation 4 and giving the deposition is being compensated by 5 Ethicon. 6 A. I -- as I said, I haven't even worked 7 that out. It has to be within a certain number of 8 hours. I don't know whether we can stretch that out 9 over months or it'll be a -- I don't know. I 10 haven't worked it out yet. 11 Q. What is the limit of the number of 12 hours that you are allowed to work under the 13 contract? 14 A. 40 per month, but I don't know 15 whether that means 80 for two months or 80 -- you 16 know, or 40 a month, period. 17 Q. I understand. That's -- that's as 18 much detail as I need, thank you. 19 Do you have a judgment how many hours 20 you've spent in preparing for giving your deposition 21 over the last couple days? 22 A. Well, I can estimate. Wednesday, we 23 spent about four hours. Last Thursday, we spent 24 maybe six or seven hours. Last Friday was about 25 five and a half hours, and I did some review at</p>
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<p>1 - - - 2 EXAMINATION 3 - - - 4 BY MR. FREESE: 5 Q. Dr. Weisberg, you testified on 6 examination for Mr. Gage that you had retired in 7 August of this year; is that correct? 8 A. Retired as a full-time employee. 9 Q. And you're now a consultant for 10 Ethicon? 11 A. Yes. 12 Q. Okay. 13 And are you being paid to be here 14 today? 15 A. I assume so. 16 Q. Okay. How much are you being paid to 17 be here? 18 A. I don't know. I'm limited to a 19 number of hours that my contract limits me to, and I 20 don't know how they're going to work that out. 21 Q. Okay. 22 You don't need to tell me the amount 23 of your contract, but whatever you're -- are you 24 paid by the hour under your contract or is it a sum 25 certain?</p>	<p>1 home. I didn't really -- I didn't really track 2 hours for that, but several -- several evenings of 3 reviewing documents. 4 Q. All right. 5 So the 20 or so hours that you're 6 saying you were preparing, not at home, you were 7 with the lawyers for Ethicon getting ready for your 8 testimony; correct? 9 A. Yes. 10 Q. Was Maha preparing you? 11 A. Maha was there, yes. 12 Q. Mr. Gage? 13 A. Yes. 14 Q. Who else? 15 A. Mr. Gage wasn't there all the time. 16 Q. And -- 17 A. I spoke to -- we brought Stacy 18 Kluesner in because I had a bunch of questions for 19 her. I spoke to Piet Hinoul for a little bit. 20 There was somebody else that came in and I don't 21 remember who it was. 22 Q. Were the lawyers always present when 23 you were speaking to Ms. Kluesner or Dr. Hinoul? 24 A. No. I spoke to Dr. Hinoul on my own 25 some of the time, and they were present for one</p>

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<p>1 phone call or two. I don't recall. 2 Q. How many times did you speak to Dr. 3 Hinoul? 4 A. I speak to him on a regular basis, so 5 I -- I can't parse out -- you know, I might have 6 thrown a question here and there in other 7 conversations. 8 Q. Did you speak to anybody not your 9 lawyers last night? 10 A. No. 11 Q. That's a bad question. Did you speak 12 to anyone other than your lawyers last night about 13 this deposition or any of the questions you've been 14 asked? 15 A. I did. 16 Q. And who's that? 17 A. I spoke to Piet. 18 Q. So after you gave your testimony 19 yesterday, you went and called Dr. Hinoul? 20 A. I did. 21 Q. And there were no lawyers on the 22 phone? 23 A. The lawyers were there. 24 Q. Okay. 25 But you did speak to Dr. Hinoul with</p>	<p>1 best of my knowledge. 2 BY MR. FREESE: 3 Q. I understand, but you're here as a 4 fact witness on behalf of the company and not as an 5 expert witness; correct? 6 A. That's what I -- 7 MR. GAGE: Object to form. 8 THE WITNESS: That's what I 9 understand. 10 MR. FREESE: All right. 11 BY MR. FREESE: 12 Q. Now, you listed for Mr. Gage -- I 13 think you said there were all kinds of RCTs 14 beginning in 1997 with the launch of TVT Retropubic. 15 Do you remember that? 16 A. Yes. 17 Q. And you said there were a 18 hundred-plus retropubic RCTs; correct? 19 A. Yes. 20 Q. And you said, starting 2004, there 21 were over 60 RCTs for TVT-O; correct? 22 A. Yes. 23 Q. And you said there were over a 24 thousand case reports, including case reports, case 25 series, and other kinds of scientific literature, on</p>
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<p>1 your lawyers on the phone last night after you gave 2 a deposition all day yesterday. 3 A. Yes. 4 Q. And how long did that call last? 5 A. Five minutes. 6 Q. Now, you are not hired by Ethicon to 7 be an expert witness in any of these cases, are you? 8 A. No. 9 Q. You've not been designated as an 10 expert? 11 A. Not -- no. 12 Q. And you're not here giving any 13 testimony as an expert witness; correct? 14 A. That's correct. 15 Q. And to the extent that any Court 16 concludes that any opinion you've rendered is that 17 of which an expert would give, you would agree with 18 me that Marty Weisberg's testimony should not be 19 given as an expert witness. 20 MR. GAGE: Object to form. 21 THE WITNESS: I think that's a legal 22 question that -- 23 MR. FREESE: It is. 24 THE WITNESS: -- the lawyers and the 25 Court have to determine. I -- I answered to the</p>	<p>1 TVT and TVT-O; correct? 2 A. That's an estimate. 3 Q. And that's all information in the 4 public domain, is it not? 5 A. That's correct. 6 Q. So it was as equally available to 7 Marty Weisberg as it was Health Canada, was it not? 8 A. Yes. 9 Q. So was there any data that was 10 available to you, scientific data that you were 11 answering Mr. Gage's question, that was not also 12 available to Health Canada? 13 MR. GAGE: Object to form. 14 THE WITNESS: I don't think so. 15 Everything was in public -- if not in the public 16 domain, was available for a price. 17 BY MR. FREESE: 18 Q. Everything you were testifying about 19 you believe was in the public domain; correct? 20 A. Yes. 21 Q. And if it's in the public domain, 22 it's equally available to Health Canada, isn't it? 23 A. Yes, it is. 24 Q. And your IFU was available to Health 25 Canada, was it not?</p>

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<p>1 A. Yes.</p> <p>2 Q. And despite their having access to</p> <p>3 the thousands of case studies, the hundreds of TVT</p> <p>4 studies, the 60 TVT-O studies, they still demanded</p> <p>5 that you make all these changes to your IFUs for</p> <p>6 your TVT family of products, didn't it?</p> <p>7 MR. GAGE: Object to form.</p> <p>8 THE WITNESS: They requested that</p> <p>9 those changes be made, yes.</p> <p>10 MR. FREESE: Even though they had</p> <p>11 access to all that same data you had; correct?</p> <p>12 THE WITNESS: I don't know whether</p> <p>13 they accessed it or not, but they had access to it.</p> <p>14 BY MR. FREESE:</p> <p>15 Q. Absolutely. And despite having</p> <p>16 access to it, Health Canada was not satisfied that</p> <p>17 your IFU was answering or providing the safety and</p> <p>18 efficacy information about the TVT family of</p> <p>19 products in its minds; correct?</p> <p>20 MR. GAGE: Object to form.</p> <p>21 THE WITNESS: I don't know what's in</p> <p>22 their minds, but they requested some changes.</p> <p>23 BY MR. FREESE:</p> <p>24 Q. You understand that they had access</p> <p>25 to that scientific data, Health Canada was not</p>	<p>1 Q. Does the FDA ever to your knowledge</p> <p>2 -- strike that.</p> <p>3 Since you've been working for</p> <p>4 Ethicon, has the FDA ever instructed Ethicon not to</p> <p>5 strengthen any of its warnings or precautions or</p> <p>6 adverse reactions of any of its products to your</p> <p>7 knowledge?</p> <p>8 A. Not that I'm aware of.</p> <p>9 Q. So a hundred percent of your</p> <p>10 experience, sir, is that if you're trying to</p> <p>11 strengthen a warning by changing the precautions,</p> <p>12 warnings, adverse events and provide more</p> <p>13 information, more detailed information, the FDA has</p> <p>14 always endorsed that practice; correct?</p> <p>15 MR. GAGE: Object to form.</p> <p>16 THE WITNESS: I don't know all the</p> <p>17 circumstances when we tried to do this, but it's my</p> <p>18 understanding that they would not object.</p> <p>19 BY MR. FREESE:</p> <p>20 Q. Okay. So as you sit here today, you</p> <p>21 can't think of a single example when the FDA</p> <p>22 objected to you strengthening a warning.</p> <p>23 A. That's correct.</p> <p>24 MR. GAGE: Object to form.</p> <p>25 BY MR. FREESE:</p>
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<p>1 satisfied that the IFUs that were used by Ethicon</p> <p>2 prior to May 29th of 2014 were adequate, was it?</p> <p>3 MR. GAGE: Object to form.</p> <p>4 THE WITNESS: That's correct.</p> <p>5 BY MR. FREESE:</p> <p>6 Q. They believed, in order to be full</p> <p>7 and fair balanced, that you needed to make the</p> <p>8 changes that your company went through to make;</p> <p>9 correct?</p> <p>10 MR. GAGE: Object to form.</p> <p>11 THE WITNESS: That's what we</p> <p>12 inferred.</p> <p>13 BY MR. FREESE:</p> <p>14 Q. Same question -- same question with</p> <p>15 respect to the FDA, Dr. Weisberg, and we're going to</p> <p>16 talk a little more about this, but all the</p> <p>17 information that you're saying was available, the</p> <p>18 scientific studies that you told Mr. Gage about,</p> <p>19 that was all available to the FDA, was it not?</p> <p>20 A. That's correct.</p> <p>21 Q. All right.</p> <p>22 And not one change did the -- that</p> <p>23 was made to the IFUs was objected to by the FDA;</p> <p>24 correct?</p> <p>25 A. That's correct.</p>	<p>1 Q. Now, you told us that you supplied</p> <p>2 some data to Health Canada; correct?</p> <p>3 A. Yes.</p> <p>4 Q. And you -- you will at least agree</p> <p>5 with me that there is scientific data that's not so</p> <p>6 complimentary of the safety of TVT products;</p> <p>7 correct? You'll give me that, won't you?</p> <p>8 A. You mean generally not --</p> <p>9 Q. Yes, sir.</p> <p>10 A. No, I think that the specifics of all</p> <p>11 the articles that talk about adverse events don't</p> <p>12 demonize the whole project -- the product.</p> <p>13 Q. I withdraw the question. It was a</p> <p>14 bad question.</p> <p>15 You will agree with me that there is</p> <p>16 scientific data demonstrating that TVTs can suffer</p> <p>17 from complications in greater numbers versus</p> <p>18 traditional surgeries.</p> <p>19 MR. GAGE: Object to form.</p> <p>20 THE WITNESS: There are some papers</p> <p>21 that say that.</p> <p>22 BY MR. FREESE:</p> <p>23 Q. Did you or anyone on behalf of</p> <p>24 Ethicon supply those to Health Canada?</p> <p>25 A. I can't speak for every article that</p>

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<p>1 was supplied because we supplied a lot of them, but</p> <p>2 we tried to supply a fair and balanced group of</p> <p>3 studies.</p> <p>4 Q. Well, that's my question and I won't</p> <p>5 go through all these with you, but Mr. Gage has a</p> <p>6 collection -- did you give us as the exhibit we</p> <p>7 discussed earlier all the submission to Health</p> <p>8 Canada?</p> <p>9 A. Yes.</p> <p>10 Q. So whatever's in there is the -- is</p> <p>11 the universe of information that Ethicon supplied to</p> <p>12 Health Canada in making its judgment as to these</p> <p>13 changes to the IFU; correct?</p> <p>14 A. Yes.</p> <p>15 Q. So I can look at them and see whether</p> <p>16 or not any negative studies were given to Health</p> <p>17 Canada; is that correct?</p> <p>18 MR. GAGE: Object to form. I think</p> <p>19 what we have marked is the TVT, not the Gynemesh PS</p> <p>20 submission. Right? Because the Gynemesh PS</p> <p>21 submission would have gone to Health Canada, too,</p> <p>22 and we didn't mark that.</p> <p>23 MR. FREESE: Well, then, let me</p> <p>24 qualify the question.</p> <p>25 MR. GAGE: Qualify the question --</p>	<p>1 articles that you would consider not complimentary</p> <p>2 of any of your products.</p> <p>3 A. You know --</p> <p>4 MR. GAGE: Object to the form.</p> <p>5 THE WITNESS: -- generally scientific</p> <p>6 literature isn't positive or negative. It includes</p> <p>7 all the findings, the successes, the failures, the</p> <p>8 adverse events, and that's how -- generally how good</p> <p>9 published scientific literature goes.</p> <p>10 Very infrequently do you see anything</p> <p>11 that -- that is a whole negative article. There's</p> <p>12 always a balance in the article of what the findings</p> <p>13 were.</p> <p>14 BY MR. FREESE:</p> <p>15 Q. And --</p> <p>16 A. And I think you'll find those.</p> <p>17 Q. And I didn't mean to suggest</p> <p>18 otherwise, Dr. Weisberg. I'm simply asking that</p> <p>19 I'll find a fair and balanced collection of data</p> <p>20 that you sent to Health Canada, the good, the bad,</p> <p>21 and the ugly.</p> <p>22 A. Yes.</p> <p>23 Q. And that's what being fair and</p> <p>24 balanced means.</p> <p>25 A. Yes.</p>
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<p>1 limit it to TVT and --</p> <p>2 MS. KABBASH: I think it was the</p> <p>3 whole thing.</p> <p>4 MR. GAGE: Is it?</p> <p>5 MS. KABBASH: I think it's the whole</p> <p>6 thing.</p> <p>7 MR. GAGE: Oh, well, I'm sorry. I</p> <p>8 thought --</p> <p>9 MS. KABBASH: I want to look at it</p> <p>10 just to be absolutely sure, but I'm pretty sure --</p> <p>11 BY MR. FREESE:</p> <p>12 Q. Well, let me ask it this way: Is it</p> <p>13 your belief as you sit here, Dr. Weisberg, that</p> <p>14 everything that was submitted to Health Canada</p> <p>15 regarding all the products at issue, the Gynemesh</p> <p>16 PS, the TVT family of products, was included in the</p> <p>17 exhibit here?</p> <p>18 A. Yes.</p> <p>19 Q. So we can look and see if there was</p> <p>20 any negative scientific data supplied to Health</p> <p>21 Canada; correct?</p> <p>22 A. Well, you can look.</p> <p>23 Q. And see whether or not it was</p> <p>24 actually a fair and balanced submission to them to</p> <p>25 see if you had included negative articles or</p>	<p>1 Q. Okay.</p> <p>2 Now, I want to ask you, at the time</p> <p>3 -- if you'll look at -- you don't have to -- you're</p> <p>4 welcome to look at it, but -- P-1636. That's the</p> <p>5 Hackman, one-page Hackman memo?</p> <p>6 A. Yes.</p> <p>7 Q. Mr. Gage showed that to you?</p> <p>8 A. Yeah, I don't think it's in here.</p> <p>9 You can ask the question. If I can answer it</p> <p>10 without the reference, I will. If not, I'll wait</p> <p>11 and find it.</p> <p>12 Q. Here's my question: Mr. Gage walked</p> <p>13 you through that memo. Am I correct?</p> <p>14 A. Yes.</p> <p>15 Q. And this -- this is what kicked off</p> <p>16 the project to modify the TVT family of products</p> <p>17 IFUs; correct?</p> <p>18 A. It wasn't a kickoff. It was part of</p> <p>19 the -- part of the regime that we go through or the</p> <p>20 regimen that we go through to try to do an</p> <p>21 evaluation.</p> <p>22 Q. It says initial product risk</p> <p>23 assessment --</p> <p>24 A. Well, yes, that's the initial product</p> <p>25 risk assessment. The risk assessment is one piece</p>

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<p style="text-align: right;">Page 542</p> <p>1 of everything else that we've done.</p> <p>2 Q. And at the time that Mr. Hackman</p> <p>3 wrote this e-mail in September of 2014, there were</p> <p>4 tens of thousands of product liability lawsuits</p> <p>5 pending against Ethicon and Johnson & Johnson at</p> <p>6 that time; correct?</p> <p>7 A. That's correct.</p> <p>8 MR. GAGE: Object to form.</p> <p>9 BY MR. FREESE:</p> <p>10 Q. So not only were you involved in this</p> <p>11 team, but a bunch of lawyers who work for Ethicon</p> <p>12 were also involved in this Health Canada response</p> <p>13 team, were they not?</p> <p>14 A. Yes.</p> <p>15 MR. GAGE: Object to form.</p> <p>16 BY MR. FREESE:</p> <p>17 Q. In fact, not only lawyers for</p> <p>18 Ethicon, but lawyers who actively manage the tens of</p> <p>19 thousands of product liability lawsuits were</p> <p>20 involved in the Health Canada response, were they</p> <p>21 not?</p> <p>22 A. Yes.</p> <p>23 MR. GAGE: Object to form.</p> <p>24 BY MR. FREESE:</p> <p>25 Q. And those same lawyers were reviewing</p>	<p style="text-align: right;">Page 544</p> <p>1 product liability lawsuits over synthetic mesh.</p> <p>2 A. He was not --</p> <p>3 MR. GAGE: Object to form.</p> <p>4 MS. KABBASH: Object to form.</p> <p>5 THE WITNESS: He was not supervised</p> <p>6 by the lawyers.</p> <p>7 BY MR. FREESE:</p> <p>8 Q. The lawyers were on the team --</p> <p>9 A. They were on the team.</p> <p>10 MR. GAGE: Object to form.</p> <p>11 THE WITNESS: They were on the team.</p> <p>12 They may well have participated. They may well also</p> <p>13 have waited for him to come up with that and see how</p> <p>14 it fit in with the rest of the project.</p> <p>15 BY MR. FREESE:</p> <p>16 Q. And, for example, when Mr. Hackman</p> <p>17 writes in here that a review of the risk assessment</p> <p>18 summaries -- and I'll paraphrase that. It's down at</p> <p>19 the bottom -- that the IFU changes introduce no new</p> <p>20 design or user-related risk, nor increase any risk</p> <p>21 levels -- that was reviewed by the team before it</p> <p>22 was sent out, was it not?</p> <p>23 A. That may not have been reviewed by</p> <p>24 the team before it was sent out because I don't --</p> <p>25 who was it sent to?</p>
<p style="text-align: right;">Page 543</p> <p>1 memos like Mr. Hackman's in September of 2014 before</p> <p>2 they got issued; correct?</p> <p>3 MR. GAGE: Object to form.</p> <p>4 THE WITNESS: I can't testify that</p> <p>5 they have reviewed that. It was certainly</p> <p>6 available. I don't know if it was sent to everyone</p> <p>7 on the team. I don't -- I -- you'd really need to</p> <p>8 check with the lawyers for that.</p> <p>9 BY MR. FREESE:</p> <p>10 Q. Well, you had no problem telling Mr.</p> <p>11 Gage that this document was created in the normal</p> <p>12 course of business, that Mr. Hackman had personal</p> <p>13 knowledge of what he was doing at the time he was</p> <p>14 doing it -- you didn't write this memo; correct?</p> <p>15 A. That's correct.</p> <p>16 Q. But you had no problem telling Mr.</p> <p>17 Gage that Mr. Hackman knew all this himself, did</p> <p>18 you? You told us that, didn't you?</p> <p>19 A. Well, he knew all of it, but he might</p> <p>20 not have known it all before he wrote that memo.</p> <p>21 Q. I understand.</p> <p>22 A. Yeah.</p> <p>23 Q. But Mr. Hackman was doing this under</p> <p>24 the supervision of the lawyers for Ethicon that were</p> <p>25 involved in defending these tens of thousands of</p>	<p style="text-align: right;">Page 545</p> <p>1 Q. It was sent to project file.</p> <p>2 A. Okay. I -- I don't know whether that</p> <p>3 was -- once again, I'm going to try to explain this.</p> <p>4 There are a lot of pieces that go</p> <p>5 into a project like this. Somebody may have said to</p> <p>6 Mr. Hackman, review the risk -- the -- you know, the</p> <p>7 risk assessment documents and make sure that</p> <p>8 everything was what he said it was.</p> <p>9 They may have taken that and may not</p> <p>10 have reviewed those risk documents themselves, but</p> <p>11 they certainly saw that letter at some point, yes.</p> <p>12 Q. The lawyers for Ethicon were looking</p> <p>13 -- if they were on the team, they were looking at</p> <p>14 project file documents, were they not? That's part</p> <p>15 of what they were looking at.</p> <p>16 A. Yes.</p> <p>17 MR. GAGE: Object to form.</p> <p>18 THE WITNESS: I just don't know</p> <p>19 whether they looked at it before he wrote it or</p> <p>20 after he wrote.</p> <p>21 BY MR. FREESE:</p> <p>22 Q. And you don't even know whether or</p> <p>23 not they wrote it themselves, do you?</p> <p>24 MR. GAGE: Object to form.</p> <p>25 THE WITNESS: I know that Hackman was</p>

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<p>1 working on it.</p> <p>2 MR. FREESE: I understand that.</p> <p>3 THE WITNESS: And I --</p> <p>4 MR. FREESE: I'm asking you a</p> <p>5 different question, sir: Do you know whether or not</p> <p>6 Mr. Hackman's e-mail on project file was written in</p> <p>7 whole or in part by lawyers for Ethicon?</p> <p>8 MR. GAGE: Object to form.</p> <p>9 MR. FREESE: Do you know that one way</p> <p>10 or the other?</p> <p>11 MR. GAGE: Object to form.</p> <p>12 THE WITNESS: I don't know that one</p> <p>13 way or the other.</p> <p>14 BY MR. FREESE:</p> <p>15 Q. Based on your knowledge, it could</p> <p>16 have been written by a lawyer; correct?</p> <p>17 MR. GAGE: Object to form.</p> <p>18 MS. KABBASH: Object to form.</p> <p>19 THE WITNESS: Based on my knowledge,</p> <p>20 I don't know who wrote it.</p> <p>21 MR. FREESE: Okay.</p> <p>22 BY MR. FREESE:</p> <p>23 Q. So you don't know if Mr. Hackman</p> <p>24 wrote it personally -- you don't have personal</p> <p>25 knowledge of that, do you?</p>	<p>1 Q. This patient brochure, Defense</p> <p>2 Exhibit No. 4, wasn't even created by Ethicon until</p> <p>3 2012, was it?</p> <p>4 A. Well, it was revised from a 2008</p> <p>5 edition.</p> <p>6 Q. I understand.</p> <p>7 A. Yes.</p> <p>8 Q. But --</p> <p>9 A. That one was created 2012.</p> <p>10 Q. So you and Mr. Gage didn't go through</p> <p>11 the discussion of what was added to this 2012</p> <p>12 edition from the older edition, did you?</p> <p>13 A. No.</p> <p>14 Q. So all those things he had you read</p> <p>15 about what are the risks, you have no idea whether</p> <p>16 or not that was in a version prior to 2012, do you?</p> <p>17 MR. GAGE: Object to form.</p> <p>18 THE WITNESS: Well, we read both of</p> <p>19 them. We read the 2008 and we read the 2012.</p> <p>20 MR. FREESE: I'm talking about this</p> <p>21 one right here, sir, Defendant's Exhibit No. 4.</p> <p>22 THE WITNESS: There were things in</p> <p>23 there that were in the 2008; correct?</p> <p>24 MR. FREESE: Well, we can look at</p> <p>25 that. But I'm asking you, you don't know what was</p>
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<p>1 MR. GAGE: Object to remember.</p> <p>2 THE WITNESS: My understanding was</p> <p>3 that he wrote it.</p> <p>4 BY MR. FREESE:</p> <p>5 Q. Did you talk to him and ask him if he</p> <p>6 wrote?</p> <p>7 A. Well, we spoke many times.</p> <p>8 Q. Did you ask him in preparation for</p> <p>9 this deposition whether he wrote this memo?</p> <p>10 A. No.</p> <p>11 MR. GAGE: Object to form.</p> <p>12 BY MR. FREESE:</p> <p>13 Q. Did you simply surmise that because</p> <p>14 his name appears on it?</p> <p>15 A. Yes.</p> <p>16 Q. Now, Mr. Gage showed you Defendant's</p> <p>17 Exhibit 4. Do you remember that?</p> <p>18 A. Yes.</p> <p>19 Q. That's one of the patient brochures,</p> <p>20 sir?</p> <p>21 A. Yes.</p> <p>22 Q. Tell us -- and he had you read from</p> <p>23 this patient brochure, did he not?</p> <p>24 A. Either I read it or he read it. I</p> <p>25 don't remember.</p>	<p>1 in Defendant's Exhibit 4 before 2012.</p> <p>2 MR. GAGE: Object to form.</p> <p>3 THE WITNESS: I don't recall off the</p> <p>4 top of my head.</p> <p>5 BY MR. FREESE:</p> <p>6 Q. I mean, they don't even look the</p> <p>7 same. They have different pictures.</p> <p>8 A. (Witness nods head.)</p> <p>9 Q. You've never sat down and did a</p> <p>10 comparison what was in Defendant's-4 versus</p> <p>11 Defendant's No. 3, did you?</p> <p>12 A. No, I didn't.</p> <p>13 Q. You simply just read what Mr. -- or,</p> <p>14 actually, you listened to Mr. Gage read it to you,</p> <p>15 didn't you?</p> <p>16 A. Yes.</p> <p>17 Q. And you are not suggesting and have</p> <p>18 no personal knowledge, Dr. Weisberg, do you, of any</p> <p>19 specific doctor in this country that received any of</p> <p>20 these patient brochures to pass out to their</p> <p>21 patients; correct?</p> <p>22 A. I can't name them, but the purpose of</p> <p>23 the brochures was to give to the physicians who were</p> <p>24 using the device.</p> <p>25 Q. I understand. And if a physician</p>

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<p>1 didn't get a patient brochure, they can't have the 2 benefit of it. Do you agree with that? 3 MR. GAGE: Object to form. 4 THE WITNESS: Well, I believe it was 5 on the Internet, also. 6 MR. FREESE: Sir, I'm -- listen to my 7 question. 8 BY MR. FREESE: 9 Q. If the patient brochure is not given 10 to the doctor and the doctor's not looking for your 11 patient brochure on the Internet, not going to have 12 that information that's contained in the hard copy; 13 correct? 14 A. That's correct. 15 Q. And you're not suggesting that any 16 particular doctor got either Defendant's Exhibit No. 17 3 or Exhibit No. 4; is that correct? 18 A. I know that they were distributed. I 19 don't know to whom or to how many. 20 Q. And there's no record in Ethicon to 21 say which doctor got which patient brochure or ever 22 got a patient brochure; correct? 23 MR. GAGE: Object to form; beyond the 24 scope. 25 THE WITNESS: If there is, I'm not</p>	<p>1 the 2015, made no material changes in the safety or 2 health risks regarding the use of the TVT products; 3 correct? 4 MR. GAGE: Object to form. 5 THE WITNESS: The -- 6 MR. FREESE: Or is it not? I'm 7 paraphrasing your testimony. Is or is that not what 8 your testimony is? 9 MR. GAGE: Object to form. 10 THE WITNESS: It made no difference 11 in the health risks, no. 12 BY MR. FREESE: 13 Q. In your view, it made no difference 14 in the health risk. It didn't supply the doctor 15 with any information they didn't already know; 16 correct? 17 A. Yes. 18 Q. In your view, it simply parroted, but 19 maybe in different language, the same warnings that 20 were already in the prior IFUs; correct? 21 MR. GAGE: Object to form. 22 THE WITNESS: That's another thing it 23 did. 24 BY MR. FREESE: 25 Q. And I guess you can agree with me,</p>
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<p>1 aware of it. 2 MR. FREESE: Okay. Thank you. 3 BY MR. FREESE: 4 Q. Now, I think you testified yesterday 5 and I think confirmed today -- and I'm looking at 6 Defense Exhibit No. 5 -- this was the -- I guess the 7 voice mail -- it started with the voice mail back 8 and forth with the FDA. 9 Do you remember that exhibit? 10 A. Yes. 11 Q. You told Mr. Gage -- 12 A. I have it. 13 Q. That's really kind of a reference 14 point. You don't necessarily need it, but you're 15 welcome to look at it. 16 You told Mr. Gage that after Health 17 Canada came in and required that these changes be 18 made to your IFUs, Johnson & Johnson and Ethicon 19 decided that you were going to go worldwide with 20 these changes; is that correct? 21 MR. GAGE: Object to form. 22 THE WITNESS: That's correct. 23 BY MR. FREESE: 24 Q. And it's your testimony, Dr. 25 Weisberg, that the -- the new versions of the IFU,</p>	<p>1 from a medical standpoint, Martin Weisberg thought 2 this was a totally unnecessary task from the 3 standpoint of providing information to doctors about 4 the safety and efficacy of your company's products. 5 A. Yes. 6 Q. Yet, once you embarked on complying 7 with Health Canada on a project that you personally 8 believed was totally unnecessary, your group, 9 including all the lawyers for the company that were 10 on the group, decided, we're going to put this 11 change worldwide in every country in which we do 12 business and sell our products; correct? 13 MR. GAGE: Object to form. 14 THE WITNESS: Correct. 15 BY MR. FREESE: 16 Q. Your IFUs are, the last time I 17 counted, translated by 25 different languages. Does 18 that sound about right? 19 A. I don't know the exact number. 20 Q. Sound about right? 21 A. It's probably right. 22 Q. In how many countries does Ethicon 23 sell TVT and Gynemesh? 24 A. I don't know. 25 Q. Over a hundred?</p>

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<p>1 A. I don't know.</p> <p>2 Q. On six continents?</p> <p>3 A. I suspect.</p> <p>4 Q. I'm going to assume you don't sell in</p> <p>5 Antarctica, but anywhere where people permanently</p> <p>6 live on this planet, these products are sold, are</p> <p>7 they not?</p> <p>8 A. Well, it's the most widely used</p> <p>9 product for this procedure.</p> <p>10 Q. And in 2015, over a totally</p> <p>11 unnecessary change, in your view, the company</p> <p>12 decided to change the IFU in every country in which</p> <p>13 you do business; correct?</p> <p>14 A. Yes.</p> <p>15 MR. GAGE: Object to form.</p> <p>16 BY MR. FREESE:</p> <p>17 Q. For every product you sold; correct?</p> <p>18 MR. GAGE: Object to form.</p> <p>19 THE WITNESS: Yes.</p> <p>20 BY MR. FREESE:</p> <p>21 Q. In every language in which it was</p> <p>22 sold under; correct?</p> <p>23 A. Yes.</p> <p>24 MR. GAGE: Object to form.</p> <p>25 BY MR. FREESE:</p>	<p>1 THE WITNESS: I don't recall that</p> <p>2 throughout the discussions. I think everybody</p> <p>3 agreed that what we added was good. Was it</p> <p>4 necessary? Probably not.</p> <p>5 BY MR. FREESE:</p> <p>6 Q. All right.</p> <p>7 And so -- and that is my question:</p> <p>8 As you sit here today, Dr. Weisberg, it's your</p> <p>9 recollection that the -- that the consensus of the</p> <p>10 Health Canada response team was that this was a</p> <p>11 unnecessary exercise that you were going through.</p> <p>12 MR. GAGE: Object to the form.</p> <p>13 THE WITNESS: It was necessary in</p> <p>14 that it's a regulatory body and they asked for it.</p> <p>15 MR. FREESE: And I apologize. That</p> <p>16 was a bad question.</p> <p>17 BY MR. FREESE:</p> <p>18 Q. It was the consensus of your Health</p> <p>19 Canada response team that from a medical safety</p> <p>20 standpoint, this was an unnecessary exercise that</p> <p>21 Health Canada was requiring you to go through.</p> <p>22 MR. GAGE: Object to form.</p> <p>23 THE WITNESS: Yes.</p> <p>24 BY MR. FREESE:</p> <p>25 Q. And you then took that unnecessary</p>
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<p>1 Q. So the company translated these IFUs</p> <p>2 into 25 or more different languages to give</p> <p>3 information that Martin Weisberg believed was</p> <p>4 totally unnecessary.</p> <p>5 A. Totally unnecessary? I think they're</p> <p>6 unnecessary, but I think there was no bad</p> <p>7 information in there. And why not?</p> <p>8 Q. Did --</p> <p>9 A. We had been -- we had been making an</p> <p>10 effort to harmonize our IFUs; and if one regulatory</p> <p>11 body says we need to put something in and there's</p> <p>12 nothing wrong with that information, why not include</p> <p>13 it?</p> <p>14 MR. FREESE: Move to strike as</p> <p>15 nonresponsive.</p> <p>16 BY MR. FREESE:</p> <p>17 Q. My question to you, Dr. Weisberg, is,</p> <p>18 did anyone on your team say, you know what, Health</p> <p>19 Canada's right, we do need to strengthen our</p> <p>20 warnings, this is -- we do have some lapses here,</p> <p>21 we've got some gaps, this is a good plan and we need</p> <p>22 to strengthen and make our warnings clearer on</p> <p>23 safety? Did anybody on your team express such a</p> <p>24 sentiment?</p> <p>25 MR. GAGE: Object to form.</p>	<p>1 work and translated it into every country, in every</p> <p>2 product, in every language in which your products</p> <p>3 are sold; correct?</p> <p>4 A. Yes.</p> <p>5 MR. GAGE: Object to form.</p> <p>6 BY MR. FREESE:</p> <p>7 Q. And, Dr. Weisberg, I -- you were</p> <p>8 handed Defense Exhibit No. 6, which was the</p> <p>9 collection of all the redline versions that went to</p> <p>10 the FDA.</p> <p>11 Do you recall that?</p> <p>12 A. Yes.</p> <p>13 Q. And Mr. Gage asked you some questions</p> <p>14 about communications between Ethicon and the FDA.</p> <p>15 You remember those questions?</p> <p>16 A. Yes.</p> <p>17 Q. And he said that the FDA never</p> <p>18 ordered you to do this; is that correct?</p> <p>19 A. That's correct.</p> <p>20 Q. And am I correct that no one in the</p> <p>21 FDA ever expressed to you or anyone else at Ethicon</p> <p>22 that it believed that this was an unnecessary</p> <p>23 exercise?</p> <p>24 That you weren't doing anything, you</p> <p>25 weren't helping out, there's no -- there's no new</p>

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Page 558	Page 560
<p>1 information here, did anyone from the FDA ever say 2 that?</p> <p>3 A. No.</p> <p>4 MR. GAGE: Object to form.</p> <p>5 BY MR. FREESE:</p> <p>6 Q. What the FDA did was, once they were 7 alerted that you were doing it, they wanted to see 8 it, they embraced it, and endorsed it; correct?</p> <p>9 A. Yes.</p> <p>10 Q. All right.</p> <p>11 And I'm going to ask you a general 12 question, Dr. Weisberg: All of these e-mails that 13 Mr. Gage showed you back and forth to the FDA and 14 you told Mr. Gage that the person had personal 15 knowledge and the e-mail was done at or about the 16 time -- you remember all those questions?</p> <p>17 A. Yes.</p> <p>18 Q. As you sit here today, you don't know 19 which, if all, of those e-mails were either written 20 by lawyers for Ethicon or reviewed by lawyers for 21 Ethicon before they were sent out.</p> <p>22 MR. GAGE: Object to form.</p> <p>23 MR. FREESE: Correct?</p> <p>24 THE WITNESS: I don't know. I know 25 the phone call was not.</p>	<p>1 Q. Who was present at the meeting when 2 you requested Ms. Kluesner to provide you this 3 document?</p> <p>4 A. The attorneys sitting in the room 5 now.</p> <p>6 Q. The two lawyers representing you now?</p> <p>7 A. Yes -- wait a minute. I -- that's a 8 -- that's a good question. Was everybody together 9 at that meeting? I don't know. But I know that 10 there was a point at which we all four were in one 11 room vetting this.</p> <p>12 Q. So when you say we were all in a room 13 vetting it, you, Ms. Kluesner, and the lawyers for 14 Ethicon were vetting your chronology.</p> <p>15 A. Yes.</p> <p>16 Q. And you don't think that Ms. Kluesner 17 supplied all these ETH.MESH. documents, do you?</p> <p>18 A. Oh, no. No, that was -- that was 19 supplied by the attorneys.</p> <p>20 Q. Yeah. So if we look through all the 21 pages 1 through 6 of your chronology, we know that 22 all the documents -- the document source, that is, 23 what supports the event, and the date was supplied 24 by the lawyers for Ethicon; correct?</p> <p>25 A. Right. I didn't request the document</p>
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<p>1 BY MR. FREESE:</p> <p>2 Q. And all of these e-mails and 3 correspondence that Mr. Gage showed you was during 4 2014 and 2015; correct?</p> <p>5 A. Yes.</p> <p>6 Q. When you know and everyone at the 7 company knows there are tens of thousands of product 8 liability lawsuits pending against your company for 9 these very products.</p> <p>10 A. Yes.</p> <p>11 MR. GAGE: Object to form.</p> <p>12 BY MR. FREESE:</p> <p>13 Q. Now, Mr. Gage showed you D-9, this 14 chronology of events?</p> <p>15 A. Yes.</p> <p>16 Q. Did any lawyer assist in the 17 preparation of Defense Exhibit No. 9?</p> <p>18 A. I requested it. I worked with Stacy 19 on it. I don't know if or what kind of input the 20 attorneys had. I just got this after I requested 21 it.</p> <p>22 Q. You requested this chronology from 23 Ms. Kluesner?</p> <p>24 A. I requested it at a meeting. The 25 attorneys were present.</p>	<p>1 sources. It was suggested that we put them in there 2 to make it easier for everybody to find the 3 documents.</p> <p>4 Q. By the lawyers.</p> <p>5 A. Yes.</p> <p>6 Q. Now, you remember Mr. Gage asked you 7 questions about your testimony yesterday -- Dr. 8 Weisberg, do you have your rough transcript from 9 yesterday?</p> <p>10 A. Is that --</p> <p>11 Q. It's what Mr. Gage showed you.</p> <p>12 A. -- this one?</p> <p>13 MR. GAGE: Yeah, that's it.</p> <p>14 THE WITNESS: I have it.</p> <p>15 MR. FREESE: Can you identify the 16 exhibit number? I don't have it --</p> <p>17 MR. GAGE: I didn't make it an 18 exhibit number, but --</p> <p>19 MR. FREESE: Okay. That's fair 20 enough.</p> <p>21 BY MR. FREESE:</p> <p>22 Q. If you'll turn to page 175, Dr. 23 Weisberg --</p> <p>24 A. Okay.</p> <p>25 Q. -- this was the testimony that --</p>

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<p>1 MR. GAGE: Hang on. Did you say 175?</p> <p>2 Oh, I'm sorry.</p> <p>3 MR. FREESE: This is how it's</p> <p>4 paginated. It's down here, 175 --</p> <p>5 MR. GAGE: It's down here at the</p> <p>6 bottom. It's 190 at the top. It's 175 at the</p> <p>7 bottom.</p> <p>8 I think he's with you.</p> <p>9 MR. FREESE: The rough pagination is</p> <p>10 page 175. Do you see that?</p> <p>11 THE WITNESS: Yes.</p> <p>12 BY MR. FREESE:</p> <p>13 Q. And then Mr. Gage asked you the</p> <p>14 question -- I'm sorry -- no -- Mr. Gage just read</p> <p>15 you this question and answer 30 minutes ago that you</p> <p>16 gave yesterday; correct?</p> <p>17 A. Yes.</p> <p>18 Q. And then he let you explain why the</p> <p>19 answer that you gave yesterday was not a correct</p> <p>20 answer; correct?</p> <p>21 A. Yes.</p> <p>22 Q. And just so the jury understands in</p> <p>23 this case, when you gave that answer, you gave it</p> <p>24 based on your best recollection of events at the</p> <p>25 time; correct?</p>	<p>1 before today.</p> <p>2 MR. GAGE: Object to form.</p> <p>3 THE WITNESS: That's not why that</p> <p>4 happened. It happened --</p> <p>5 MR. FREESE: Dr. Weisberg, I'm not</p> <p>6 asking you why. I'm saying, you didn't change the</p> <p>7 answer to that question until after you took a break</p> <p>8 yesterday with your lawyers and came back today and</p> <p>9 changed it when Mr. Gage asked you the question. Am</p> <p>10 I correct?</p> <p>11 MR. GAGE: Object to form.</p> <p>12 MR. FREESE: I'm just asking sequence</p> <p>13 of events, sir.</p> <p>14 MR. GAGE: Object to form.</p> <p>15 THE WITNESS: Yes.</p> <p>16 BY MR. FREESE:</p> <p>17 Q. Okay. And the same question on --</p> <p>18 you were asked by -- I don't want to ask that.</p> <p>19 Strike that. Now, just a couple more questions, Dr.</p> <p>20 Weisberg, and I'm going to be done.</p> <p>21 First of all, you understand that --</p> <p>22 or maybe you don't understand it, but I represent a</p> <p>23 woman named Jennifer Ramirez in Bear County, Texas.</p> <p>24 Did you know that before today?</p> <p>25 A. I knew that Jennifer Ramirez was one</p>
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<p>1 A. Yes.</p> <p>2 Q. And you had three lawyers sitting in</p> <p>3 here yesterday, did you not?</p> <p>4 A. Yes.</p> <p>5 Q. Before a break was taken, you did not</p> <p>6 change that answer in any way, did you?</p> <p>7 A. I don't believe so.</p> <p>8 Q. We then took a break and you and the</p> <p>9 three lawyers for Ethicon went out of this room,</p> <p>10 came back, and after that 30-minute break, attempted</p> <p>11 to amend this answer to this question. Am I</p> <p>12 correct?</p> <p>13 A. That's correct.</p> <p>14 MR. GAGE: Object to form.</p> <p>15 BY MR. FREESE:</p> <p>16 Q. The same is true with the question</p> <p>17 you were asked about the foreign body reaction, the</p> <p>18 chronic foreign body reaction -- do you remember --</p> <p>19 A. Yes.</p> <p>20 Q. -- you gave that answer multiple</p> <p>21 times yesterday, but you only changed it today after</p> <p>22 you've had a chance to meet with your lawyers last</p> <p>23 night; correct?</p> <p>24 MR. GAGE: Object to form.</p> <p>25 MR. FREESE: After the deposition and</p>	<p>1 of the plaintiffs.</p> <p>2 Q. You don't know Jennifer Ramirez, do</p> <p>3 you?</p> <p>4 A. No.</p> <p>5 Q. You do not know Cesar Reyes, her</p> <p>6 doctor, do you?</p> <p>7 A. No.</p> <p>8 Q. He's the doctor, I'll represent, that</p> <p>9 implanted a TVT-O in Ms. Ramirez. Okay. Did you</p> <p>10 know that before today?</p> <p>11 MR. GAGE: Object to form.</p> <p>12 THE WITNESS: I don't know what -- I</p> <p>13 don't think I knew that. I may have known it --</p> <p>14 BY MR. FREESE:</p> <p>15 Q. You don't know Dr. Reyes.</p> <p>16 A. No.</p> <p>17 Q. You don't know what patient brochure,</p> <p>18 if any, Dr. Reyes has ever seen; correct?</p> <p>19 A. That's correct.</p> <p>20 Q. And you don't know what version of</p> <p>21 the TVT Obturator IFU Dr. Reyes saw; is that</p> <p>22 correct?</p> <p>23 A. That's correct.</p> <p>24 Q. Now, am I also correct that the IFU</p> <p>25 must, of necessity, be written so it can be</p>

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<p>1 understood by the least-skilled surgeon who is</p> <p>2 capable of performing the surgery; is that a fair</p> <p>3 statement?</p> <p>4 MR. GAGE: Object to form.</p> <p>5 THE WITNESS: Yes.</p> <p>6 BY MR. FREESE:</p> <p>7 Q. Because you and I understand that</p> <p>8 there are doctors who perform pelvic surgeries for</p> <p>9 SUI and pelvic organ prolapse that are double</p> <p>10 board-educated urogynecologists, fellowship-trained,</p> <p>11 all the way down to gynecologists who have no</p> <p>12 fellowships, who have no board certifications.</p> <p>13 You understand the universe of</p> <p>14 doctors that implant your product runs from very</p> <p>15 sophisticated to less sophisticated, less educated,</p> <p>16 less trained physicians; is that a fair statement?</p> <p>17 MR. GAGE: Object to form.</p> <p>18 THE WITNESS: Yes.</p> <p>19 BY MR. FREESE:</p> <p>20 Q. And you would agree with me that the</p> <p>21 information, the safety information, that's</p> <p>22 necessary for a doctor to perform a pelvic organ</p> <p>23 surgery or a SUI sling surgery, they all need to</p> <p>24 have a minimum amount of ability; correct?</p> <p>25 A. Yes.</p>	<p>1 THE WITNESS: Yes.</p> <p>2 BY MR. FREESE:</p> <p>3 Q. Because you assume that every doctor</p> <p>4 implanting your company's products has a -- some</p> <p>5 baseline adequate amount of training and medical</p> <p>6 knowledge in order to perform it; correct?</p> <p>7 A. Yes.</p> <p>8 Q. And you wouldn't waste the doctor's</p> <p>9 time warning them about things that, as you've</p> <p>10 described, any pelvic surgeon would know; correct?</p> <p>11 MR. GAGE: Object to form.</p> <p>12 THE WITNESS: Waste the doctor's time</p> <p>13 isn't an expression I would use, but it wouldn't be</p> <p>14 necessary.</p> <p>15 BY MR. FREESE:</p> <p>16 Q. Right. And I think you said that</p> <p>17 there are certain things that all doctors know.</p> <p>18 That's why you don't put all the warnings in the</p> <p>19 IFU, because there is a -- there's a presumption at</p> <p>20 Johnson & Johnson that there's a baseline of</p> <p>21 information that all doctors would have, and anyone</p> <p>22 doing pelvic surgery would know that, so we don't</p> <p>23 have to warn them about it; correct?</p> <p>24 MR. GAGE: Object to form.</p> <p>25 THE WITNESS: Yes.</p>
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<p>1 Q. Because that's one of the changes you</p> <p>2 recommended, right, that the doctor be properly</p> <p>3 trained; correct?</p> <p>4 MR. GAGE: Object to form.</p> <p>5 THE WITNESS: I believe that's always</p> <p>6 been there.</p> <p>7 BY MR. FREESE:</p> <p>8 Q. And you've added that patient</p> <p>9 selection is something that needs to be considered</p> <p>10 more thoroughly now; correct?</p> <p>11 MR. GAGE: Object to form.</p> <p>12 THE WITNESS: I believe that was</p> <p>13 added somewhere along the line.</p> <p>14 BY MR. FREESE:</p> <p>15 Q. The doctor needs to consider the</p> <p>16 specifics of the patient in deciding whether or not</p> <p>17 it's an appropriate indicated use for, say, a TVT-O</p> <p>18 sling; correct?</p> <p>19 A. Yes.</p> <p>20 Q. And I think you told Mr. Gage that --</p> <p>21 that the IFU is not intended to warn about all</p> <p>22 risks. It's just risks that are -- that are</p> <p>23 peculiar or unique to your particular product;</p> <p>24 correct?</p> <p>25 MR. GAGE: Object to form.</p>	<p>1 BY MR. FREESE:</p> <p>2 Q. Now, do you have one -- the IFU in</p> <p>3 front of you, sir? This may be from yesterday's --</p> <p>4 1649 is the one I'd like you to look at because this</p> <p>5 is the TVT-O system.</p> <p>6 A. Would it be down here? 1639, 1649.</p> <p>7 Got it.</p> <p>8 Q. In the contradictions, it's page 20</p> <p>9 -- ETH.MESH.27 is the last -- on the bottom</p> <p>10 right-hand corner? If you'll just go to</p> <p>11 contraindications section --</p> <p>12 A. 2027 is the cover sheet?</p> <p>13 MR. GAGE: Oh, he's --</p> <p>14 MR. FREESE: The last two. I'm just</p> <p>15 reading the last two of the Bates stamp number.</p> <p>16 MR. GAGE: That's the one -- it's on</p> <p>17 the same page. Look up at the second number.</p> <p>18 MR. FREESE: 32 then.</p> <p>19 MR. GAGE: 32? There you go.</p> <p>20 THE WITNESS: Okay.</p> <p>21 BY MR. FREESE:</p> <p>22 Q. So 1649, this is the newest, best</p> <p>23 version or most-current version we have of the TVT</p> <p>24 Obturator IFU; correct?</p> <p>25 MR. GAGE: Objection to form.</p>

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<p>1 THE WITNESS: Revision 5, let me just 2 check that real fast. 3 MR. FREESE: Sure. 4 THE WITNESS: Is there a revision 6 5 in the wind? I don't know. Do you have that -- did 6 somebody take my IFU release page? 7 MR. BARLOW: Just so we don't get 8 crossed up, that is the -- we marked two copies of 9 the 2015, you know, post-Health Canada. That is not 10 the version that is on the sheet -- it's the one 11 that we looked at and everybody seemed to agree -- 12 MS. KABBASH: And I think Adam did 13 the questioning yesterday, and he covered both, so 14 -- 15 MR. BARLOW: Right. 16 MR. GAGE: So -- so he's ready to go. 17 We're ready. 18 THE WITNESS: Yes. 19 BY MR. FREESE: 20 Q. If you'll look in contraindications, 21 it says: As with any suspension surgery, this 22 procedure should not be performed in pregnant 23 patients. Additionally, because Prolene 24 polypropylene will not significantly stretch, it 25 should not be performed in patients with future</p>	<p>1 didn't you? 2 A. Yes, we did. 3 Q. Do not use Gynecare TVT Obturator in 4 a patient who has a urinary tract infection. 5 A. Correct. 6 Q. Why don't you want to do that? 7 A. You don't want to operate in an 8 infected area. 9 Q. Do you think most pelvic surgeons 10 would know that you don't want to operate in an 11 infected area? 12 A. Yes. 13 Q. Yet, you put that in the IFU; 14 correct? 15 A. Yes. 16 Q. Users should be familiar with 17 surgical technique for urethral suspensions and 18 should be adequately trained in Gynecare TVT 19 Obturator procedure before employing Gynecare TVT 20 Obturator device, do you see that? 21 A. Yes. 22 Q. Do you think a surgeon needs to be 23 told that he needs to know what he is doing before 24 he does it? 25 A. No.</p>
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<p>1 growth -- 2 A. Potential. 3 Q. -- potential, including women with 4 plans for future pregnancy. 5 Is that a fact that most surgeons 6 would not know? 7 A. It's a contraindication. I think 8 most surgeons would know it. 9 Q. So you think most surgeons would know 10 that. 11 A. I would think so. 12 Q. Yet, it's in your IFU; correct? 13 A. Yes. 14 Q. Warnings and precautions: Do not use 15 Gynecare Obturator in patients who are on 16 anticoagulation therapy. Do not use Gynecare TVT 17 Obturator in a patient who has urinary tract 18 infection. 19 Why don't you want to use a TVT-O on 20 someone on anticoagulation therapy? 21 A. Because they bleed. 22 Q. Do you think a pelvic floor surgeon 23 would know that without being told in your IFU? 24 A. I think so. 25 Q. Yeah, but you put it in there anyway,</p>	<p>1 Q. But that's in your IFU. 2 A. Yes. 3 Q. Acceptable surgical practice should 4 be followed for the procedure, as well as for the 5 management of concomitant -- is it contaminated 6 infected wounds? 7 A. Yes. 8 Q. Do most pelvic surgeons know that? 9 A. Yes. 10 Q. Do they need to be told that they 11 need to use acceptable surgical practices? 12 A. No. 13 Q. Yet, that found its way into your 14 IFU. 15 A. That's right. 16 Q. The procedure should be performed 17 with care to avoid large vessels, nerves, bladders, 18 and bowel. Attention to patient anatomy and correct 19 passage of the device will minimize the risk, do you 20 see that? 21 A. Yes. 22 Q. Do you need to tell a pelvic floor 23 surgeon that -- 24 A. No. 25 Q. -- avoid cutting nerves or other</p>

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<p>1 organs or blood vessels?</p> <p>2 A. No.</p> <p>3 Q. Okay.</p> <p>4 If you need to tell a surgeon that,</p> <p>5 he doesn't need to have a scalpel in his hand, does</p> <p>6 he?</p> <p>7 A. You're right.</p> <p>8 Q. Bleeding may occur postoperatively,</p> <p>9 do you need to tell pelvic surgeons that bleeding</p> <p>10 may be a result in a warning and a precaution from a</p> <p>11 TVT surgery?</p> <p>12 A. No.</p> <p>13 Q. Although bladder injury is unlikely</p> <p>14 to occur with this technique, cystoscopy may be</p> <p>15 performed at the discretion of the surgeon, does</p> <p>16 every pelvic floor surgeon know that?</p> <p>17 A. Probably.</p> <p>18 Q. But you put it in your IFU anyway.</p> <p>19 A. That's right.</p> <p>20 Q. Do not remove the plastic sheath</p> <p>21 until the tape has been properly positioned, does</p> <p>22 every pelvic floor surgeon know that?</p> <p>23 A. They should know that.</p> <p>24 Q. Okay. But that made it into your</p> <p>25 IFU, too.</p>	<p>1 Some may want to know about vaginal</p> <p>2 delivery following this, and what we're basically</p> <p>3 telling them is, we don't really know, but at least</p> <p>4 we're answering a question that we would frequently</p> <p>5 get.</p> <p>6 I think that it's important to know</p> <p>7 that if there is leg pain for 24 to 48 hours, that</p> <p>8 it is likely to resolve.</p> <p>9 They may want to know whether they</p> <p>10 should prescribe prophylactic antibiotics. We say</p> <p>11 it's their choice.</p> <p>12 Q. A physician reading this would think</p> <p>13 that leg pain is not likely going to last more than</p> <p>14 24-48 hours, are they?</p> <p>15 MR. GAGE: Object to the form.</p> <p>16 THE WITNESS: And that's what happens</p> <p>17 in the majority of cases.</p> <p>18 BY MR. FREESE:</p> <p>19 Q. And in a significant number of cases,</p> <p>20 women have leg pain beyond 24 or 48 hours with</p> <p>21 obturator surgeries, do they not?</p> <p>22 MR. GAGE: Object to form.</p> <p>23 THE WITNESS: Not significant</p> <p>24 compared to the number that have been done.</p> <p>25 BY MR. FREESE:</p>
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<p>1 A. Yes.</p> <p>2 Q. Ensure the tape is placed with no</p> <p>3 tension under the mid-urethra, does pelvic floor</p> <p>4 surgeons know that, that they don't need to tension</p> <p>5 it?</p> <p>6 A. Well, those who did the pretape</p> <p>7 slings procedures put them in with tension, so this</p> <p>8 is something that somebody new to this device may</p> <p>9 need to be reminded.</p> <p>10 Q. Okay. So that's the first one that</p> <p>11 actually you think somebody may -- a pelvic floor</p> <p>12 surgeon might need to be reminded about.</p> <p>13 A. Yes.</p> <p>14 Q. Do not perform this procedure if you</p> <p>15 think the surgical site may be infected or</p> <p>16 contaminated, do you need to tell a surgeon that?</p> <p>17 A. No.</p> <p>18 Q. Let me ask you this, Dr. Weisberg:</p> <p>19 Is there anything in the warnings and precautions</p> <p>20 that you think any pelvic floor surgeon wouldn't</p> <p>21 know?</p> <p>22 A. Yeah, I think that somebody new to</p> <p>23 this might ask if there's any information about</p> <p>24 pregnancy following this procedure. That's in</p> <p>25 there.</p>	<p>1 Q. So how many women have to have</p> <p>2 permanent leg pain, Dr. Weisberg, in your opinion,</p> <p>3 before it becomes a significant amount to Ethicon?</p> <p>4 MR. GAGE: Object to form.</p> <p>5 THE WITNESS: I don't have an answer</p> <p>6 for that.</p> <p>7 MR. FREESE: Okay.</p> <p>8 BY MR. FREESE:</p> <p>9 Q. This is your newest version of the</p> <p>10 IFU for TVT Obturator, isn't it?</p> <p>11 A. Yes.</p> <p>12 Q. And it's still telling doctors using</p> <p>13 this TVT-O approach, you should expect a transient</p> <p>14 leg pain of 24 to 48 hours and it will resolve with</p> <p>15 using mild analgesics; correct?</p> <p>16 MR. GAGE: Object to form.</p> <p>17 THE WITNESS: That's what happens</p> <p>18 most of the time.</p> <p>19 MR. FREESE: That's like Advil.</p> <p>20 Right?</p> <p>21 THE WITNESS: Yes.</p> <p>22 BY MR. FREESE:</p> <p>23 Q. Dr. Weisberg, is there a single</p> <p>24 contraindication, a single warning or precaution or</p> <p>25 a single adverse reaction that you think a normal</p>

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<p>1 pelvic floor surgeon with just normal, adequate 2 training would not know and needs to be informed of 3 via this IFU? 4 MR. GAGE: Object to form and 5 objection, asked and answered. 6 THE WITNESS: We discussed some that 7 I thought that they might need to be -- need to know 8 or to be reminded. 9 MR. FREESE: I know. 10 THE WITNESS: But for the most part, 11 I think they know most of this. 12 BY MR. FREESE: 13 Q. So for the most part, this is a -- is 14 a -- the document itself is meaningless and 15 worthless in your mind. 16 A. Not at all. 17 MR. GAGE: Object to form. 18 BY MR. FREESE: 19 Q. Because it doesn't inform a doctor of 20 anything that you believe he doesn't already know or 21 should know; correct? 22 MR. GAGE: Object to form. 23 THE WITNESS: If you look at the 24 first several pages of the document, it explains how 25 to use this device.</p>	<p>1 THE WITNESS: This -- most of this 2 stuff is very basic and would fit into that 3 least-skilled category. 4 BY MR. FREESE: 5 Q. And you've not read Dr. Reyes' 6 deposition, have you? 7 A. I have not. 8 Q. You do not know what he said about 9 the IFU and what his knowledge was, do you? 10 A. I do not. 11 MR. FREESE: Dr. Weisberg, I think 12 that's all I have. I appreciate your time, sir. 13 THE WITNESS: Thank you. 14 MR. FREESE: One question. 15 BY MR. FREESE: 16 Q. The FDA -- the FDA recommended that 17 you not use two adverse reactions sections, did it 18 not? 19 A. Correct. 20 Q. Just out of curiosity, because I'm 21 here, you ignored that request of the FDA and didn't 22 follow the recommendation, because you included two 23 separate adverse reactions sections in the final 24 IFU; correct? 25 MR. GAGE: Object to form.</p>
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<p>1 MR. FREESE: I'm sorry. I apologize. 2 You didn't understand my question or I asked a bad 3 question. 4 THE WITNESS: I think I understood 5 it. 6 BY MR. FREESE: 7 Q. I'm asking you -- no, I asked a bad 8 question, I'll admit that. 9 With respect to the precautions, the 10 warnings, and adverse reactions, you believe that's 11 all surplusage. It's unnecessary because you 12 believe all doctors already know or should know 13 everything contained in those sections; correct? 14 MR. GAGE: Object to form and 15 objection, asked and answered. 16 THE WITNESS: I believe for the most 17 part -- and we spoke about some specifics -- for the 18 most part, people who understand how to do pelvic 19 surgery and incontinence surgery already know 20 everything in this list. 21 BY MR. FREESE: 22 Q. But we agreed that you've gotta have 23 the -- you've gotta be at the level of the 24 least-skilled capable and adequate surgeon; correct? 25 MR. GAGE: Object to form.</p>	<p>1 THE WITNESS: My understanding is 2 that we did what they asked and we combined them. 3 MR. FREESE: 1649 has two versions -- 4 has -- 5 THE WITNESS: Well, if we could look 6 at the redlined version we sent them, we might get a 7 better idea of how we are going to do this. 8 BY MR. FREESE: 9 Q. It's your belief that 1649 is not the 10 final-final of the TVT-O IFU? 11 MR. GAGE: Object to form. 12 THE WITNESS: It may be that -- that 13 the new one hasn't been printed yet. I don't -- 14 BY MR. FREESE: 15 Q. But you think they've been combined? 16 A. I believe they have been combined. 17 MR. FREESE: Thank you. I have no 18 further questions. I think Mr. Barlow may have a 19 few questions. Thank you, sir. 20 (Pause.) 21 - - - 22 EXAMINATION 23 - - - 24 BY MR. BARLOW: 25 Q. Doctor, Ethicon doesn't know what any</p>

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<p>1 given implanting doctor knows or doesn't know about 2 the adverse reactions that can occur with regard to 3 its mesh products when they go to perform an implant 4 surgery, do they? 5 MR. GAGE: Object to form. 6 THE WITNESS: They don't know 7 specifically what each doctor knows. 8 BY MR. BARLOW: 9 Q. Exactly. 10 And I believe you testified that 11 Ethicon has not performed any scientific study to 12 determine what pelvic floor surgeons know or don't 13 know about the adverse reactions that can occur with 14 their pelvic mesh products, do they -- have they? 15 A. That's correct. 16 Q. And Ethicon hasn't performed any 17 scientific survey with regard to what pelvic floor 18 surgeons may know or not know about the adverse 19 effects that can happen with regard to their pelvic 20 mesh products; correct? 21 MR. GAGE: Object to form. 22 THE WITNESS: I believe that's 23 correct, but I'm not sure. 24 BY MR. BARLOW: 25 Q. To your knowledge -- you're not aware</p>	<p>1 iteration of the IFU? 2 A. I believe it is. 3 Q. How is that documented? 4 A. It will be in the design history 5 file. 6 Q. It'll be -- is there a particular 7 thing that that's called? 8 A. Design -- it would be under the 9 design validation section, the IFU design validation 10 section. 11 Q. And how many surgeons are typically 12 brought in for this sort of thing? 13 A. It depends. There's usually a few 14 sessions, with 10 or 12 in each session. 15 Q. So we're talking about a few dozen? 16 A. Yeah. 17 Q. But there's tens of thousands of 18 surgeons that perform these surgeries in the United 19 States; correct? 20 A. Well, that's true. 21 MR. GAGE: Object to form. 22 BY MR. BARLOW: 23 Q. So whatever focus group type thing is 24 done with the IFUs, that's not a scientific survey 25 or study, is it?</p>
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<p>1 of any scientific survey of what doctors know or 2 don't know about the adverse reactions for your 3 pelvic mesh products. Right? 4 MR. GAGE: Object to form. 5 THE WITNESS: The only -- the only 6 answer I can give you is that all of our IFUs are 7 looked at by a panel of people that we bring in to 8 look at the IFUs, the panel of doctors, and get 9 their opinions on it and ask them whether they -- 10 this is adequate for them. 11 BY MR. BARLOW: 12 Q. And these IFUs are reviewed by -- are 13 they key opinion leaders that you all bring in? 14 A. Not necessarily. They're just -- 15 it's a range of people. 16 Q. Are they doctors that are brought in 17 that Ethicon feels have significant expertise in the 18 area of pelvic floor surgery? 19 A. There's a range. There's a range of 20 people -- even sometimes residents, people who are 21 new in practice, people who are key opinion leaders. 22 We try to get a range of these people for these -- 23 Q. Is that -- 24 A. -- these sessions. 25 Q. I'm sorry. Is that done for every</p>	<p>1 MR. GAGE: Object to form. 2 THE WITNESS: It's not scientific. 3 BY MR. BARLOW: 4 Q. Doctor, will you pull out -- just 5 take a look at 1635, which is the memo to the 6 project file that purports to be from Lee Hackman? 7 A. I don't know if we ever found it, but 8 go ahead. I know that memo. 9 Q. Okay. I'm just going to ask you, it 10 says: The proposed IFU changes consist of enhancing 11 the current IFUs to better describe known product 12 risk or to include hazards not currently identified 13 in the IFUs. 14 Do you agree with that? 15 A. That's the task of this -- this 16 particular form that he's -- that he's working with. 17 Q. Do you agree that the new IFUs better 18 describe the known product risk? 19 A. Yes. 20 Q. And do you believe that they include 21 hazards not currently identified in the IFUs? 22 A. Well, the hazards that they add are 23 not spelled out in the old IFUs; but once again, 24 these were things that we assume are common 25 knowledge.</p>

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<p>1 Q. Okay. Fair -- setting aside your 2 assumptions about what doctors may or may not know, 3 do the new IFUs include hazards that were not 4 previously identified in the IFUs? 5 A. Hazards that are spelled out more 6 specifically, yes. 7 Q. So we're in agreement that the new 8 IFUs better describe product risk; correct? 9 A. Yes. 10 Q. Doctor, you would agree with me then 11 that the language found on -- in Exhibit 1640 with 12 regard to the TVT adverse reactions better describes 13 those adverse reactions than what was found in the 14 IFUs prior to the 2015 revisions; correct? 15 MR. GAGE: Object to form. 16 THE WITNESS: Yes. 17 MR. BARLOW: What's the -- what's the 18 objection, Bill? 19 MR. GAGE: The phrase "better 20 describe" is vague and ambiguous. 21 MR. BARLOW: That's fine. 22 MR. FREESE: Let it go. 23 BY MR. BARLOW: 24 Q. Doctor, the language regarding 25 foreign body response with regard to TVT adverse</p>	<p>1 adverse reaction than what is in your IFUs; correct? 2 MR. GAGE: Object to form. 3 THE WITNESS: Yes. 4 BY MR. BARLOW: 5 Q. And, Doctor, the language with regard 6 to acute and/or chronic pain, from Exhibit 1640, an 7 IFU that includes that better describes that adverse 8 risk than what was in your IFUs; correct? 9 A. Yes. 10 MR. GAGE: Object to form. 11 BY MR. BARLOW: 12 Q. With regard to pain with intercourse, 13 which may in some patients not resolve, that 14 language -- an IFU that includes that language would 15 better describe that adverse reaction than what was 16 in your IFUs; correct? 17 A. Yes. 18 MR. GAGE: Object to form. 19 BY MR. BARLOW: 20 Q. Doctor, with regard to neuromuscular 21 problems, including acute and/or chronic pain in the 22 groin, thigh, leg, pelvic and/or abdominal area, an 23 IFU for a TVT-O that -- or -- a TVT-O that includes 24 that language would better describe that adverse 25 reaction than what was in your TVT-O IFUs; correct?</p>
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<p>1 reactions that's found in 1640, an IFU that included 2 that language would better describe that adverse 3 reaction than for the -- with the IFUs without it; 4 correct? 5 MR. GAGE: Object to form. 6 THE WITNESS: I'm sorry. I don't 7 understand the question. 8 MR. BARLOW: Sure. 9 BY MR. BARLOW: 10 Q. With regard to the IFUs that we've 11 discussed, excluding -- excluding the IFUs that came 12 out this year, okay, all of my questions going 13 forward are going to be about the IFUs prior to the 14 Health Canada. Okay? 15 A. Okay. 16 Q. Doctor, the language -- well, an IFU 17 that includes the language regarding foreign body 18 response from Exhibit 1640 better describes that 19 adverse reaction than in your IFUs; correct? 20 MR. GAGE: Object to form. 21 THE WITNESS: Correct. 22 BY MR. BARLOW: 23 Q. And the language regarding mesh 24 extrusion, exposure, or erosion into the vagina or 25 other structures or organs better describes that</p>	<p>1 MR. GAGE: Object to form. 2 THE WITNESS: Yes. 3 BY MR. BARLOW: 4 Q. With regard to neuromuscular 5 problems, including acute and/or chronic pain in the 6 groin, thigh, leg, pelvic and/or abdominal area, an 7 IFU for an Abbrevio that included that language would 8 better describe that adverse reaction than your 9 Abbrevio IFUs; correct? 10 MR. GAGE: Object to form. 11 THE WITNESS: Yes. 12 BY MR. BARLOW: 13 Q. With regard to TVT, original TVT, 14 neuromuscular -- an IFU that included the language 15 neuromuscular problems, including acute and/or 16 chronic pain in the groin, pelvic and/or abdominal 17 area, would better describe -- would better describe 18 that adverse reaction than what was in your TVT 19 IFUs; correct? 20 A. Yes. 21 MR. GAGE: Object to form. 22 BY MR. BARLOW: 23 Q. With regard to the TVT Exact, an IFU 24 that included the language neuromuscular problems, 25 including acute and/or chronic pain in the groin,</p>

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<p>1 pelvic and/or abdominal area would -- an IFU that 2 included that language would better describe that 3 adverse reaction than what was in your Exact IFUs; 4 correct? 5 A. Yes. 6 MR. GAGE: Object to form. 7 THE WITNESS: Yes. 8 BY MR. BARLOW: 9 Q. An IFU that includes that these 10 adverse reactions may require surgical treatment 11 would better describe that risk than what was in 12 your previous IFUs; correct? 13 MR. GAGE: Object to form. 14 THE WITNESS: Yes. 15 BY MR. BARLOW: 16 Q. A -- an IFU that includes the 17 language, one or more revision surgeries may be 18 necessary to treat these adverse reactions, would 19 better describe that risk than what was in your 20 previous IFUs; correct? 21 MR. GAGE: Object to form. 22 THE WITNESS: Yes. 23 BY MR. BARLOW: 24 Q. Doctor, an IFU that included the 25 language, in cases in which Prolene mesh needs to be</p>	<p>1 A. Yes. 2 Q. What about urinary frequency, would 3 that better describe? 4 MR. GAGE: Object to form. 5 THE WITNESS: That would better 6 describe. Even though it's included in the 7 detrusor, there are other things that cause 8 frequency. 9 BY MR. BARLOW: 10 Q. An IFU that included the -- an 11 explicit statement of de novo urinary frequency that 12 may result from the sling would better describe that 13 risk than what was in your IFUs; correct? 14 MR. GAGE: Object to form. 15 THE WITNESS: Not the sling. The 16 procedure in which the sling was used. 17 MR. BARLOW: The use of the sling. 18 THE WITNESS: Yes. 19 BY MR. BARLOW: 20 Q. Doctor, an IFU that set forth that 21 there may be de novo urinary retention as a result 22 of the use of the sling would be better than what 23 was -- would better describe that risk than what was 24 in your IFUs; correct? 25 A. Yes.</p>
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<p>1 removed in part or whole, significant dissection may 2 be required -- an IFU that includes that language 3 would better describe that risk than what is -- what 4 was in your IFUs; correct? 5 A. Yes. 6 MR. GAGE: Object to form. 7 THE WITNESS: Yes. 8 BY MR. BARLOW: 9 Q. And, Doctor, an IFU that included the 10 language that, even with additional surgeries, the 11 adverse reactions may not resolve, would better 12 describe that risk than what was in your previous 13 IFUs; correct? 14 MR. GAGE: Object to form. 15 THE WITNESS: Yes. 16 BY MR. BARLOW: 17 Q. Doctor, an IFU that sets forth that 18 urge -- de novo urge incontinence may result from 19 the implantation of your devices would better 20 describe that risk than your previous IFUs; correct? 21 A. No. 22 MR. GAGE: Object to form. 23 THE WITNESS: No. 24 BY MR. BARLOW: 25 Q. Because of the detrusor language?</p>	<p>1 MR. GAGE: Object to form. 2 THE WITNESS: Yes. 3 I keep doing that. I'm sorry. 4 MR. GAGE: She's getting it. 5 BY MR. BARLOW: 6 Q. An IFU that set forth that de novo 7 urinary obstruction could occur as a result of the 8 use of the sling would better describe that risk 9 than what was in your IFUs; correct? 10 MR. GAGE: Object to form. 11 THE WITNESS: No. I think urinary 12 obstruction is handled. 13 BY MR. BARLOW: 14 Q. Doctor, an IFU that set forth that 15 voiding dysfunction -- de novo voiding dysfunction 16 could result from the use of the sling would better 17 describe that risk than what was in your IFUs; 18 correct? 19 MR. GAGE: Object to the form. 20 THE WITNESS: I don't think so. 21 MR. BARLOW: Okay. You disagree on 22 that one. 23 BY MR. BARLOW: 24 Q. With regard to the Gynemesh PS, a IFU 25 that included that de novo urinary incontinence</p>

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<p>1 could result would better describe that risk than 2 what was in your IFUs; correct? 3 MR. GAGE: Object to form. 4 THE WITNESS: Yes. 5 BY MR. BARLOW: 6 Q. An IFU that included that de novo 7 urge incontinence could result from the use of the 8 Gynemesh PS would better describe that risk than 9 what was in your IFUs; correct? 10 MR. GAGE: Object to form. 11 THE WITNESS: I'm sorry. I need to 12 look at the Gynemesh IFU. 13 MR. BARLOW: Yes, sir. Be my guest. 14 THE WITNESS: Do we have one 15 available? 16 MR. BARLOW: Yeah, I'm -- you have 17 them in the exhibits. I don't -- 18 MR. GAGE: Do you know what the 19 number is? 20 MR. BARLOW: Not off the top of my 21 head. 22 THE WITNESS: Yeah, I'll give you a 23 number. 24 MR. GAGE: They're in the add file. 25 Is that here?</p>	<p>1 formality, so... 2 MR. GAGE: I'm sending you all my 3 hotel bill for tonight and I'm going to send you 4 text messages all night long. I'm going to have 5 people come pound on your hotel door -- 6 MR. BARLOW: I'm almost done. This 7 is my last line of questioning. 8 MR. FREESE: I'm not keeping you from 9 going to get your flight. 10 MR. BARLOW: Maha can handle this. 11 MR. FREESE: She's chomping at the 12 bit. 13 MR. BARLOW: She can say object to 14 form every bit as good as you, I promise. 15 MR. GAGE: Probably better. 16 THE WITNESS: Unfortunately, I need 17 an old one and I'm trying to figure out whether -- 18 MR. GAGE: That's redlined -- 19 THE WITNESS: Yeah, it's redlined. 20 It should work. I'm trying to figure out whether 21 there's any reference to detrusor instability, and I 22 don't believe that there is -- 23 MR. GAGE: Oh, I see what you're 24 saying. 25 THE WITNESS: -- because I don't</p>
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<p>1 MS. KABBASH: If you look at the 2 redline, you can tell. You can tell by the redline 3 -- 4 MR. GAGE: So why don't we put that 5 one at the top. 6 THE WITNESS: That's the only one I 7 need to look at. 8 MR. GAGE: Okay. 9 MS. KABBASH: That's our copy. 10 MR. GAGE: So I'm going to keep it 11 inside the rubber band so it's still the composite 12 exhibit -- 13 MS. KABBASH: That's our copy -- 14 MR. GAGE: That's our copy. 15 MS. KABBASH: -- so it doesn't 16 matter. 17 MR. GAGE: Oh, okay. So it doesn't 18 matter. I'm going to let him look at our copy. 19 MR. BARLOW: Yeah, that's fine. 20 MR. GAGE: So that we don't disturb 21 the pristineness of the original composite, such as 22 it were. 23 MR. BARLOW: You will learn over, 24 hopefully, the years, hopefully not in this 25 particular litigation, that I don't stand on</p>	<p>1 believe that the Gynemesh should lead to detrusor 2 instability. 3 Okay. I can answer your question. 4 MR. BARLOW: Okay. Now I don't even 5 remember what it was. Which one was I on? 6 BY MR. BARLOW: 7 Q. Doctor, an IFU that included that de 8 novo urge incontinence could result from the use of 9 Gynemesh PS would better describe that risk than 10 your IFUs; correct? 11 A. Yes, although the risk is low. 12 Q. I'll tell you what, Doctor, on 1632, 13 Exhibit 1632 -- do you have that in front of you? 14 Don't worry about it. It'll be quicker for me to do 15 it this way. 16 An IFU that said that de novo urinary 17 frequency could result from the use of Gynemesh PS 18 would better describe that risk than what was in 19 your IFUs; correct? 20 A. Yes. 21 MR. GAGE: Object to form. 22 THE WITNESS: I'm sorry. 23 BY MR. BARLOW: 24 Q. And an IFU that said that de novo 25 urinary retention could result from the use of</p>

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<p style="text-align: right;">Page 598</p> <p>1 Gynemesh PS would better describe that adverse 2 reaction better than what was in your IFUs; correct? 3 MR. GAGE: Object to form. 4 THE WITNESS: Yes. 5 BY MR. BARLOW: 6 Q. A IFU that included that de novo 7 urinary obstruction could result from the use of 8 Gynemesh PS would better describe that risk than 9 what was in your IFUs; correct? 10 MR. GAGE: Object to form. 11 THE WITNESS: Yes. 12 BY MR. BARLOW: 13 Q. An IFU that included an adverse 14 reaction listing of de novo voiding dysfunction that 15 could result from the use of Gynemesh PS would 16 better describe that risk than what was in your 17 IFUs; correct? 18 MR. GAGE: Object to form. 19 THE WITNESS: Yes. 20 BY MR. BARLOW: 21 Q. A IFU that included the language 22 regarding the foreign body response resulting in 23 inflammation, extrusion, erosion, exposure, and 24 fistula formation from the use of Gynemesh PS would 25 better describe that adverse reaction than what was</p>	<p style="text-align: right;">Page 600</p> <p>1 THE WITNESS: -- that it doesn't 2 trigger -- does not trigger inflammation. 3 BY MR. BARLOW: 4 Q. Doctor, a Gynemesh PS IFU that 5 included mesh extrusion, exposure, and erosion into 6 the vagina or other structures or organs from the 7 use of Gynemesh PS would better describe that 8 adverse reaction than what was in your IFUs; 9 correct? 10 MR. GAGE: Object to form. 11 THE WITNESS: Better, but very 12 unnecessary. 13 MR. BARLOW: Object to the 14 nonresponsive portion of the answer. 15 BY MR. BARLOW: 16 Q. Doctor, a IFU that listed acute 17 and/or chronic pain would better describe that risk 18 than what was in your Gynemesh PS IFUs; correct? 19 A. Yes. 20 MR. GAGE: Object to form. 21 THE WITNESS: Yes. 22 BY MR. BARLOW: 23 Q. Doctor, a IFU that included that 24 pelvic pain, which in some patients may not resolve, 25 would better describe that adverse reaction than</p>
<p style="text-align: right;">Page 599</p> <p>1 in your IFUs; correct? 2 MR. GAGE: Object to form. 3 THE WITNESS: I believe that that was 4 in the original Gynemesh. 5 BY MR. BARLOW: 6 Q. That would have been the language 7 that would have had to do with transitory foreign 8 body response; correct? 9 A. I believe so. 10 Q. Okay. 11 Then let me amend that to say that 12 one that said that chronic foreign body response 13 could result from the use of Gynemesh PS would 14 better describe that risk than what was in your 15 IFUs; correct? 16 MR. GAGE: Object to form. 17 THE WITNESS: Chronic foreign body 18 response in itself doesn't lead to those late 19 complications. 20 BY MR. BARLOW: 21 Q. Okay. And that's because you believe 22 that the chronic foreign body response is not strong 23 enough; correct? 24 A. Well -- 25 MR. GAGE: Object to form.</p>	<p style="text-align: right;">Page 601</p> <p>1 what was in your Gynemesh PS IFUs; correct? 2 MR. GAGE: Object to form. 3 THE WITNESS: Yes. 4 BY MR. BARLOW: 5 Q. An IFU that said -- that stated that 6 pain with intercourse, which in some patients may 7 not resolve, would better describe that adverse 8 reaction than what was in your Gynemesh PS IFUs; 9 correct? 10 MR. GAGE: Object to form. 11 THE WITNESS: Yes. 12 BY MR. BARLOW: 13 Q. Doctor, an IFU that included that 14 excessive contraction or shrinkage of the tissue 15 surrounding the mesh resulting in vaginal scarring, 16 vaginal tightening, and vaginal shortening would 17 better describe that risk than what was in your 18 Gynemesh PS IFUs; correct? 19 MR. GAGE: Object to form. 20 THE WITNESS: Yes. 21 BY MR. BARLOW: 22 Q. An IFU that stated that neuromuscular 23 problems, including acute and/or chronic pain in the 24 groin, pelvic and/or abdominal area could result 25 from the Gynemesh PS would better describe that</p>

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<p>1 adverse reaction than what was in your IFUs; 2 correct? 3 MR. GAGE: Object to form. 4 THE WITNESS: Yes. 5 BY MR. BARLOW: 6 Q. An IFU that stated that the adverse 7 reactions related to the Gynemesh PS may require 8 surgical treatment would better describe that risk 9 than what was in your IFUs; correct? 10 MR. GAGE: Object to form. 11 THE WITNESS: Yes. 12 BY MR. BARLOW: 13 Q. An IFU that said, one or more 14 revision surgeries may be necessary to treat the 15 complications resulting from the Gynemesh PS, would 16 better describe that potential adverse reaction than 17 what was in your IFUs; correct? 18 MR. GAGE: Object to form. 19 THE WITNESS: Yes. 20 BY MR. BARLOW: 21 Q. An IFU that says, in cases in which 22 the Gynemesh needs to be removed in part or whole, 23 significant dissection may be required, would better 24 describe that adverse reaction than what was in your 25 Gynemesh PS IFUs; correct?</p>	<p>1 reactions. There's nothing wrong with them. They 2 weren't inaccurate. When we thought they were, we 3 didn't add them. 4 And because it was requested and 5 because the information is good, we added it. Was 6 it necessary? I don't think so, but they were good. 7 MR. BARLOW: Object to the 8 nonresponsive portion of the answer. 9 BY MR. GAGE: 10 Q. You were just asked as to whether the 11 changes to the IFU better described various 12 potential adverse reactions. Do you recall those 13 questions? 14 A. Yes. 15 Q. How many, if any, of those adverse 16 reactions were discussed in patient brochures dating 17 back to 2008 and/or 2012? 18 MR. BARLOW: Object to form. 19 THE WITNESS: Most of them. 20 BY MR. GAGE: 21 Q. Did the new IFUs use different 22 wording than the old IFUs? 23 A. Yes. 24 Q. Was that different wording used to 25 describe some of these adverse events associated</p>
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<p>1 MR. GAGE: Object to form. 2 THE WITNESS: Yes. 3 BY MR. BARLOW: 4 Q. And, Doctor, one that -- an IFU that 5 said that even with revision surgery, or multiple 6 revision surgeries, the adverse reactions or 7 complications may not be cured would better describe 8 that adverse reaction or risk than what was in your 9 Gynemesh PS IFUs; correct? 10 MR. GAGE: Object to form. 11 THE WITNESS: Yes. 12 MR. BARLOW: Okay. I'm going to pass 13 the witness. 14 - - - 15 EXAMINATION 16 - - - 17 BY MR. GAGE: 18 Q. Dr. Weisberg, if you thought the 19 changes that we've been discussing to the IFUs and 20 brochures were unnecessary, why did you do it? 21 A. They were requested by a regulatory 22 body who hold our license. They were all accurate 23 -- all accurate additions, all accurate -- I'm 24 trying to think of the word -- they helped explain 25 some of these reactions, some of these adverse</p>	<p>1 with these devices? 2 MR. BARLOW: Object to form. 3 THE WITNESS: Yes. 4 BY MR. GAGE: 5 Q. Were the IFUs prior to 2015 6 adequate -- 7 MR. BARLOW: Object to form. 8 BY MR. GAGE: 9 Q. -- or inadequate to describe the 10 adverse reactions associated with those devices? 11 MR. BARLOW: Sorry. Object to form. 12 THE WITNESS: I believe they were 13 adequate. 14 MR. GAGE: Nothing further. 15 MR. BARLOW: We're off the record. 16 THE VIDEO TECHNICIAN: The time is 17 4:41. We're off the record. 18 (Witness excused.) 19 - - - 20 (A discussion off the record 21 occurred.) 22 - - - 23 (Whereupon, the following discussion 24 off the videotape record occurred: 25 MS. KABBASH: The deposition of Marty</p>

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<p style="text-align: right;">Page 606</p> <p>1 Weisberg has completed for the day. Maha Kabbash 2 and Alex Barlow have remained to go through and we 3 have gone through all of the exhibits, Plaintiffs' 4 exhibits, from the deposition to determine and 5 identify which ones are subject to the stipulation 6 that counsel discussed earlier in the day. 7 And we're going to read into the 8 record the exhibit numbers of the exhibits that are 9 subject to the stipulation: Those exhibits are 10 P-1608, P-1609, P-1610, P-1611, P-1612, P-1614, 11 P-1615, P-1616, P-1617, P-1618, P-1619, P-1620, 12 P-1621, P-1622, P-1625, P-1626, P-1627, P-1629, 13 P-1630, P-1631, P-1633, P-1634, P-1635, P-1636, 14 P-1639, P-1642 through P-1657, and P-1659 through 15 P-1665, P-1667, P-1668, and P-1669. 16 And, Alex, do you agree those are the 17 documents that are subject to the stipulation? 18 MR. BARLOW: I do agree. 19 MS. KABBASH: Okay. We're done on 20 the record. Thank you.) 21 (Deposition concluded at 22 approximately 5:06 p.m.) 23 24 25</p>	<p style="text-align: right;">Page 608</p> <p>1 INSTRUCTIONS TO WITNESS 2 3 Please read your deposition over 4 carefully and make any necessary corrections. You 5 should state the reason in the appropriate space on 6 the errata sheet for any corrections that are made. 7 After doing so, please sign the 8 errata sheet and date it. 9 You are signing same subject to the 10 changes you have noted on the errata sheet, which 11 will be attached to your deposition. 12 It is imperative that you return the 13 original errata sheet to the deposing attorney 14 within thirty (30) days of receipt of the deposition 15 transcript by you. If you fail to do so, the 16 deposition transcript may be deemed to be accurate 17 and may be used in court. 18 19 20 21 22 23 24 25</p>
<p style="text-align: right;">Page 607</p> <p>1 CERTIFICATE 2 3 I, KIMBERLY A. CAHILL, a Notary 4 Public and Certified Court Reporter of the State of 5 New Jersey, do hereby certify that prior to the 6 commencement of the examination, MARTIN WEISBERG, 7 M.D. was duly sworn by me to testify to the truth, 8 the whole truth and nothing but the truth. 9 I DO FURTHER CERTIFY that the 10 foregoing is a verbatim transcript of the testimony 11 as taken stenographically by and before me at the 12 time, place and on the date hereinbefore set forth, 13 to the best of my ability. 14 I DO FURTHER CERTIFY that I am 15 neither a relative nor employee nor attorney nor 16 counsel of any of the parties to this action, and 17 that I am neither a relative nor employee of such 18 attorney or counsel, and that I am not financially 19 interested in the action. 20 21 22 23 KIMBERLY A. CAHILL, CCR, RMR 24 Notary Number: 2160369 25 Notary Expiration: February 20, 2019 CCR Number: 30XI00188400 Dated: November 20, 2015</p>	<p style="text-align: right;">Page 609</p> <p>1 - - - - - 2 E R R A T A 3 - - - - - 4 PAGE LINE CHANGE/REASON 5 _____ 6 _____ 7 _____ 8 _____ 9 _____ 10 _____ 11 _____ 12 _____ 13 _____ 14 _____ 15 _____ 16 _____ 17 _____ 18 _____ 19 _____ 20 _____ 21 _____ 22 _____ 23 _____ 24 _____ 25 _____</p>

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ACKNOWLEDGMENT OF DEPONENT

I, _____, do
 hereby certify that I have read the foregoing
 pages, 293 - 611, and that the same is a correct
 transcription of the answers given by me to the
 questions therein propounded, except for the
 corrections or changes in form or substance,
 if any, noted in the attached Errata Sheet.

 MARTIN WEISBERG, M.D. DATE

Subscribed and sworn
 to before me this
 ____ day of _____, 20____.
 My commission expires: _____

 Notary Public

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LAWYER'S NOTES

PAGE LINE

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